The history and enforcement of the Federal Food, Drug, and Cosmetic Act since 1938

William Ebert Morrissey

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By

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BACKGROUND OF PRESENT LAW

In undertaking a recent history of such a fundamental law as one that deals with food, drugs and cosmetics in its relationship to the human race, we should realize that such a field has a history possibly as old as man himself. There have always been individuals interested in the good and welfare of others, and there have always been individuals interested in taking advantage of their fellow man for personal gain, frequently in an exceedingly unscrupulous manner.

The Solicitor General of the United States, in a recent paper read at the commemoration of the fortieth anniversary of the original Federal Food and Drugs Act of 1906, pointed out that "the attempts of organized society to prevent the adulteration of food and drugs date back to ancient times. The racket implicit in the purveying of adulterated and misbranded commodities is not a new one by any means -- it has been practiced from the commencement of recorded time."\(^1\) The official goes on and recites specific instances, telling how Pliny the Elder complained of "white earth" in his bread, the pepperers and spicers of London in the year 1316 began to regulate the quality of their produce, brewers were subject to fines for adulterating beer

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in the days of William the Conqueror, food control statutes were passed in France and Germany in the thirteenth century. The first pharmacopoeia was published in England by the College of Physicians in 1613. In the fourteenth century the Prevost of Paris forbade the artificial coloring of butter. In the United States, Congress enacted a law to prevent the importation of adulterated and spurious drugs and medicine as far back as 1848.2

The Department of Agriculture through its Division (later Bureau) of Chemistry from 1863 to 1906 in its reports kept calling to the attention of the various Secretaries of Agriculture, and in a measure to the attention of Congress and the people of the United States, the need for remedying conditions of food and drug frauds perpetrated upon the consumer.

The Chief Chemist, Mr. Peter Collier, in his 1880 report recommended the enactment of a national food and drug law. For he then said:

... A law carefully framed is greatly needed in this country, where adulterations are every day practiced. ... Laws should be made and vigorously enforced making the adulteration of foods and medicines a criminal offense. Where life and health are at stake no specious argument should prevent the speedy punishment of those unscrupulous men who are willing, for the sake of gain, to endanger the health of unsuspecting purchasers.3

2 Ibid., pp. 361-362.
Mr. Collier was followed by Dr. Harvey W. Wiley in 1883 as head of the Division (later Bureau) of Chemistry. Dr. Wiley immediately began a long, authoritative and historic series of food adulteration investigations by the Division and Bureau, which developed into their major action, and the results of which were published in bulletins of great public value. In 1888 President Cleveland characterized their publication as "the most complete treatise on that subject that has been published in any country." And in 1892 the Secretary of Agriculture said that "the amount of chemical work which has been done (by the Division) on this subject is perhaps the largest of any similar chemical work anywhere in the history of science."5

This historic series of investigations directed by Dr. Wiley clearly proved the need for a broad national law against adulteration or misbranding of food and drugs. Dr. Wiley repeatedly recommended such a law in his annual reports. For example, in the 1898 report he said: "The necessity of national legislation on this subject has long been apparent, for it is evident that State laws, however excellent and well executed, cannot realize their full

4 Ibid., p. 310.
5 Ibid.
purpose without the supplement of federal legislation."\(^6\)

The public had to be awakened and aroused to stir Congress into action to pass the 1906 Act. Such books and articles as these played their part in arousing public opinion: Upton Sinclair in his novel "The Jungle", which purported to portray conditions in packing plants in Chicago; in 1904 and 1905 Edward W. Bok published a series of exposures about patent medicines in his "Ladies Home Journal"; Samuel Hopkins Adams in 1905 did likewise in "Collier's Weekly".\(^7\) Many newspapers carried stories about the food scandals of the Spanish-American War.

Meanwhile, President Theodore Roosevelt was throwing all of his powerful influence behind the proposed legislation. In his annual message to the Congress on December 5, 1905, he said:

> I recommend that a law be enacted to regulate interstate commerce in misbranded and adulterated foods, drinks and drugs. Such a law would protect legitimate manufacture and commerce, and would tend to secure the health and welfare of the consuming public. Traffic in foodstuffs which have been debased or adulterated so as to injure or to deceive should be forbidden.\(^8\)

In those brief but forceful sentences, the President not only put his great prestige and vigorous support behind

\(^6\) Ibid., pp. 310-311.


\(^8\) Ibid., p. 46.
the movement for a food and drug act, but he identified its philosophy and prophesied its future. It would, he said, "protect legitimate manufacture and commerce" and "tend to secure the health and welfare of the consuming public"; it should prohibit traffic which was designed to "injure health or to deceive purchasers". So, the Food and Drugs Act was intended to be an economic as well as a public health law.9

By 1913, the Secretary of Agriculture felt that the Act of 1906 was already inadequate. The 1906 Act lacked legal standards set up for food, a broad definition of the word "drug", had innocuous penalties for violations, did not provide for factory inspections, and possessed no jurisdiction over false and misleading advertisements. Upon request of the Chairman of the House Committee on Interstate and Foreign Commerce, the Secretary made certain recommendations to remedy these weaknesses. It was not until 1938 that the suggestions made by the Secretary in 1913 were, in the main, incorporated in the present law.10

The fight to remedy these weaknesses and abuses came to a head with the advent of President Franklin D. Roosevelt and the New Deal. Leading the fight were government officials and such interested organizations as the National

9 Ibid., pp. 46-49.

10 Ibid., pp. 55-58.
League of Women Voters, American Association of University
Women, The American Federation of Labor, National Congress
of Parents and Teachers, American Dietetic Association,
American Home Economics Association, American Nurses As-
sociation, Girls Friendly Society, Homeopathic Medical So-
ciety, Medical Women's National Association, National Board
of the Young Women's Christian Association, National Council
of Jewish Women, National Women's Trade Union League, Dis-
trict of Columbia Federation of Women's Clubs, National
Women's Christian Temperance Union.11

Among the most active and forceful government officials
was Rexford Guy Tugwell, then Assistant Secretary of Agri-
culture (1933), who initiated the first bill, the "Tugwell
Bill", that would completely revise the 1906 law. Another
leader was a United States Senator from New York State,
Royal S. Copeland, a trained and practicing medical doctor
and state public health official before he became a Senator.
He undertook to sponsor and steer through Congress the Cope-
land Bill that finally passed after many revisions and com-
promises and became the present Federal Food, Drug, and
Cosmetic Act.

President Franklin Delano Roosevelt, in a special mes-
sage to Congress on March 22, 1935, strongly urged the
enactment of a new Food and Drugs Act, saying:

11 R. de F. Lamb, American Chamber of Horrors, p. V.
Every enterprise in the United States should be able to adhere to the simple principle of honesty without fear of penalty on that account. ... In one field of endeavor there is an obvious means to this end which has been too long neglected: the setting up and careful enforcement of standards of identity and quality for the foods we eat and the drugs we use, together with the strict exclusion from our markets of harmful or adulterated products. ... The various qualities of goods require a kind of discrimination which is not at the command of consumers. They are likely to confuse outward appearance with inward integrity. ... No comprehensive attempt at reform in the regulation of commerce in food and drugs has been made since 1906. ... It is time to make practical improvements. ... It is my hope that such legislation may be enacted at this session of Congress.12

The following groups were actively opposed to changes in the law during its five years of committee hearings until it finally did become the law in spite of opposition. The Proprietary Association with 201 firm members, the Institute of Medicine Manufacturers which also includes the United Medicine Manufacturers of America, Inc., with a regular firm membership of 145, and an associate membership of 70, made up of glass manufacturers, advertising agencies, trade publications and printers.13

An observation of Kathryn H. Stone, First Vice President of the National League of Women Voters, in a recent address, is both interesting and revealing:

... You have also probably been reminded today that the fight presented particular difficulties because

12 Ibid., pp. 332-334.
13 Ibid., p. V.
the usual channels for building public opinion were closed. Only three newspapers in the country gave the (Copeland) bill their consistent support, the "St. Louis Dispatch", the "Christian Science Monitor", and Wm. Allen White's "Emporia Gazette". It probably had arrayed against it as formidable a lobby as eye ever took up cudgels against a piece of legislation.14

It is not the main purpose of this paper to go into detail about the "fight" in and out of Congress that took place leading up to the actual passage of the present Food, Drug, and Cosmetic Act. This material has been amply and extensively covered by authors of repute, government publications, and magazine articles that are published by special interests as well as those for the everyday lay reader.

However, in passing I will insert three quotations to illustrate the type of arguments used by those in favor of a new law.

A consultant to the Food and Drug Administration, in discussing objectives of the present law, while it was still a bill in Congress, had this to say:

The bill is intended to strengthen and extend the Federal Food and Drugs Act of June 30, 1906. ... Since the passage of that law, profound changes in methods of manufacturing and selling foods and drugs have resulted from developments in scientific, technological and economic fields. These changes have not been devoid of opportunities for the unscrupulous to profit, without contravening the provisions of the present law, by endangering the public health and defrauding the consumer. Court decisions

have revealed textual weaknesses in the measure that were not foreseen when it was enacted. ... Yet the confidence the law has inspired in food and drug products imposes a corresponding responsibility that it may be made adequate to meet modern conditions. The bill has been prepared with this end in view. ... 15

At the climax of the legislative fight on the Copeland Bill an official of the Food and Drug Administration:

... complains at the light fines assessed against offenders by the average court. Fines as light as $1 or $2 were frequently assessed ... for serious offenses against the law. Heavy fines were often remitted. ... The court has a perfect right to disregard expert testimony and to do as it pleases in such cases. ... Consequently the expert stands on equal footing with the ignoramus in court, for all men are equal there. ... The judge may indeed plead a defendant's ignorance and lack of scientific knowledge as a sound reason for his acquittal. 16

Another writer referring to the tragic "elixir of sulfanilamide" deaths in 1937 reported:

... Physicians saw a topsy-turvy nightmare turned into a reality. Their patients died from a drug which they had prescribed because it promised miraculous cures. Even the doctors did not know until too late that this 'elixir', which was not an elixir at all, carried a deadly solvent as well as the new drug sulfanilamide. ... The government could proceed against the makers of the fatal 'elixir' solely because it was mislabeled. ... It is worthy of note that, shocking as these instances have been, the actual toll in deaths and permanent injury from potent drugs is probably far less than that resulting from harmless nostrums offered for


serious disease conditions. ...\textsuperscript{17}

The Copeland Pure Food, Drug, and Cosmetic Bill had an uphill fight every bit of the way during the five year struggle for more effective federal legislation. Patent medicine and advertising interests fought it every step of the way, but an aroused public opinion would not be denied. On June 25, 1938, the measure was signed by the President and became law.\textsuperscript{18}

\textsuperscript{17} Hillier Kriehbaum, "Have They Died in Vain?" \textit{Survey Graphic}, XXVII, 271, (May 1938).

\textsuperscript{18} Salthe, \textit{op. cit.}, p. 209.
CHAPTER II

SCOPE AND PROVISIONS OF THE PRESENT LAW

The Federal Food, Drug, and Cosmetic Act and General Regulations for its Enforcement covers fifty pages of small print. This chapter will concern itself primarily with a brief discussion of the scope and provisions of the law and regulations. For further details the reader is referred to the appendix and to the printed copy attached to the inside back cover of the thesis.

The new Act, in general, has control over all cosmetics, except toilet soap; prohibits traffic in food which may be injurious in any way to health; requires label declarations of artificial coloring, flavoring and chemical preservatives in food, exempts butter, cheese, and ice cream from this requirement. Its labeling requirements demand truthful labeling in ordinary as well as dietary foods. The same applies to official, non-official, and new drugs. New drugs can only be sold to the trade by permit from the FDA. It further prescribes the use of containers for foods, drugs, and cosmetics. And it has the right to make and enforce sanitary inspections of all products under its jurisdiction.¹

Control over advertising is specifically given to the Federal Trade Commission, therefore the present Food, Drug,

and Cosmetic Act has no control over advertising of products which are otherwise under its jurisdiction.\(^2\) Further, the Act does not bar the manufacture, as such, of misbranded or adulterated goods. Powerless at law to stop the adulteration or misbranding of foods and drugs at their source, Food and Drug officials make "multiple seizures" as soon as a product moves in interstate commerce.\(^3\)

More shortcomings in the present law are the lack of requiring of any technical qualifications for medicine manufacturers or in their employees. Nor can industries request Food and Drug Inspectors to supervise the packing of their product, as do the seafood packers. No declaration of ingredients is required on cosmetic labels; no emergency permit control is provided for the manufacture of drugs, devices, or cosmetics. Exemption from the standards provisions of the law is made for dried fruits. No requirement indicating degree of quality above standard is required in the labeling of foods in the present Act.\(^4\)

It is apparent that, even though the present pure food and drug law is a vast improvement over the old one, the new one is not as comprehensive or as effective in the

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\(^4\) Ibid., p. 22.
public interest as it could be.

The distinctly new provisions in the current law do the following things: brings under control "slenderizing" drugs; prohibits traffic in new drugs until adequately tested; protects consumers against fake contraptions, such as "electric" belts; defines and establishes standards of identity and quality for food; sets up safeguards against poisonous foods; increases criminal penalties for violations; all in the interest of the honest manufacturer as well as the consumer.

As a part of the new law there was a clause in it that postponed the enforcement of certain provisions of the law for one year, or until June 25, 1939; and certain other provisions were non-enforceable until July 1, 1940. Some interesting things happened in the interval between June 25, 1938 and July 1, 1940 which will be related presently. First, those general provisions which were not postponed and took effect June 25, 1938.

Due to the sulfanilamide tragedy, any person introducing a new drug for sale had to file with the Secretary of Agriculture an application which must contain complete information on the chemical contents of the drug, the proportions used, and any chemical reactions which took place between the drugs. The Secretary has authority to permit or

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prevent sale through a restraining order.

Two other provisions effective at once were the prohibition of drugs which were dangerous to the consumer when used as prescribed on the label, and a prohibition of cosmetics which may be injurious to the users.6

Postponement of a goodly number of the provisions of the Food, Drug, and Cosmetic Act was requested by various business interests on the grounds it would work an economic hardship upon them. As a defense for their position it was pointed out that the merchandise already manufactured and sold to the various channels of trade under the existing (Wiley) law would be almost a total financial loss. Further the printing of new labels and the correct bottling and packaging of goods could not be completed within a year's period of time, they contended.

The postponement issue wound up on the floor of Congress. According to Mr. Wallace, then Secretary of Agriculture: "In some instances the sentiment for postponement is being fostered by those who opposed the enactment of the law who appear to be unreconciled to compliance with its consumer-protective features."7

Representative Lea of California seemed to be able to


find a lot of reasons for postponing the effective date of the Federal Food, Drug, and Cosmetic Act. These reasons were reflected in the bill which Lea proposed and put through, under which certain provisions of the act would remain unenforceable until July 1, 1940.8

Certain Ohio and Tennessee representatives actually proposed that Dr. Nathan Tucker's Asthma Specific be exempt from the provisions of the law altogether. It was a matter of record that the American Medical Association had condemned it as a quack medicine. Further, in 1911, the FDA had successfully prosecuted the owners of this remedy for violating the Wiley Law. The bill exempting the Specific almost passed the House of Representatives on a bit of parliamentary strategy.9

The following provisions took effect on June 25, 1939: those relating to cosmetics, therapeutic devices, underweight and overweight drugs; required adequate testing of new drugs; increased penalties for violations; provided authority for the Federal courts to restrain violations by injunctions; eliminate the necessity for proving fraudulent intent in the labels of patent medicines; requires habit or hypnotic drugs to bear warnings to that effect; and requires the labels of non-official drugs to list the

8 Ibid.
9 Ibid.
names of active ingredients.10

These provisions, in respect to foods, did not become effective until January 1, 1940. The provisions requiring the certification of all coal-tar colors used in food; labels bearing name and address of manufacturer, packer, or distributor; whereby foods had to meet a standard of identity, fill or quality; the calling of foods by their common names; the showing of two or more ingredients on the label; the proper labeling of dietary foods; and the provision requiring artificial color, flavoring, or chemical preservative must be on the label.11

Provisions regarding drugs and devices effective the same date were these: the requirement that coal-tar colors had to be certified by the FDA; that drug labels have proper names and addresses; that labels contain warnings of habit forming ingredients; that the drug be labeled by its common name, and list ingredients if it is made up of two or more; that labels state exactly the amount of ingredients; that labels give adequate directions for use; provides for proper packaging, and stating of warnings regarding deterioration.12


12 Ibid.
Postponed until July 1, 1940, as far as enforcement was concerned, were the provisions prohibiting the use of non-certified coal-tar colors in cosmetics; and the requirement that the label on cosmetics have the name and address of the manufacturer, packer, or distributor.\textsuperscript{13}

These were the chief provisions of the Copeland Law as originally passed. Subsequent amendments have been designed mainly to bring new products under its provisions. Typical were the amendments which brought insulin and penicillin under its control. It is to be noted that these amendments were not preceded by a five year fight previous to enactment, or an eighteen month "stalling" procedure before the law could operate properly and adequately.\textsuperscript{14}

This, in general, is what the present Food, Drug, and Cosmetic Act attempts to cover. In spite of its limitations, and its handicaps along the way, the law has been accepted for what it is, and has had no serious legal obstacles to overcome in the last seven years.

\textsuperscript{13} Ibid.

\textsuperscript{14} "Legislation and Regulation-Making Activities," Annual Reports Food and Drug Administration 1941-1942-1943, p. 7.

To carry out the provisions of such a comprehensive and technical law as the present Food, Drug, and Cosmetic Act necessitates a plan of organization that is both unusual and distinctive in its operation.

Originally any food and drug laws enacted by Congress were placed under the jurisdiction of the Bureau of Chemistry, a separate research and fact finding bureau of the government with extremely limited police powers. Following the passage of the Wiley Law, the Bureau of Chemistry was taken over and nominally directed by the Secretary of Agriculture.

On July 1, 1927, the Bureau of Chemistry was incorporated into the Food, Drug, and Insecticide Administration, later called the Food and Drug Administration. By June 30, 1940, the Food and Drug Administration was transferred from the Department of Agriculture to the Federal Security Agency. At the same time the title of Chief of the Food and Drug Administration was changed to Commissioner of Food and Drugs.¹

With Mr. Watson B. Miller as present Administrator of the Federal Security Agency, and Dr. Paul B. Dunbar as the

present Commissioner of the Food and Drug Administration an outline of the organization of the Food and Drug Administration follows by title, as the individuals occupying the various posts change from time to time:
**Organization of the Food and Drug Administration**

**Federal Security Agency**

**Administrator**

**Food and Drug Administration**

**Commissioner of Food and Drugs**

- Associate Com.
- Assistant Com.
- Assistant Com.
- Medical Director
- Executive Officer

**Washington Offices**

- Cosmetic Div.
- Food Div.
- Interstate Div.
- Medical Div.
- Microbiological Div.
- Div. of Penicillin Control and Immunology
- Div. of State Cooperation
- Vitamin Div. (Each Div. has a Chief.)

**Field Service**

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<th>Central District</th>
<th>Western District</th>
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<td>San Francisco, Cal.</td>
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<td>Atlanta Station</td>
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Subsidiary to the various main stations are sixteen sub-stations located within large centers of population giving complete nation-wide coverage insofar as their budgetary funds will permit.

In discharging its technical, administrative, and regulatory duties the personnel of FDA includes chemists, bacteriologists, physicians, veterinarians, microscopists, pharmacologists, inspectors, clerks, and administrative officers. The staff totals about 600 in the field and 300 at headquarters in Washington, D. C.

The Field Service.

Geographically, the field service has three inspection districts: roughly, the Atlantic Seaboard is the eastern district; the Mississippi Valley, the central; and the Rocky Mountain and Pacific slope areas, the western. These three regions have laboratory facilities located in strategic cities within their areas.

The station headquarters are manned by inspectors and analysts whose training permits shifting from routine enforcement to cope with emergencies if they should arise. Each station is responsible for the enforcement of the law within its own area.


5 Ibid., p. 1.
Washington Staff.

The Washington staff is headed by the Commissioner who directs and coordinates regulatory activity in Washington and the entire United States as well. In this task he is assisted by the heads of the several administrative and technical divisions. The technical divisions are the Vitamin, Bacteriology, Pharmacology, Microanalytical, Food, Drug, and Cosmetic Divisions.6

Administrative Divisions.

The Interstate Division is an administrative office which assists the Commissioner in planning and directing enforcement activities. This division, with the approval of the Commissioner, possesses the power of final decision in all regulatory and enforcement activities of the Administration.

The Import Division, working with the Division of Customs of the Treasury Department, is responsible for the enforcement of the Tea Act, the Import Milk Act, and the import section of the Food, Drug, and Cosmetic Act.7

Subject-Matter Divisions.

The Food Division engages in analytical, investigation- al, regulatory problems, and formulates the food standards

6 Ibid., p. 2.
7 Ibid., pp. 2-3.
that the food industry must comply with.

The Drug Division is headquarters for technical information on questions of medicine, physiology, therapeutics, or pathology as they relate to foods, cosmetics, drugs, and therapeutic devices. It also engages in the same type of activities as the Food Division.

The Cosmetic Division is divided into two sections, one for color certification and the other for cosmetic analysis. The work of these divisions is primarily research in nature, always on the lookout for poisonous ingredients.\(^8\)

**Specialized Technical Divisions.**

The Vitamin Division's main duty is determining the validity of vitamin claims on products. This division is constantly conducting research related to the development of satisfactory methods of vitamin determination.\(^9\)

The Bacteriological Division endeavors to protect public health in the detecting of decomposition in foods, ascertaining the presence of filth and sewage pollution, solving bacteriological problems in sea foods, and examining and recommending drugs and cosmetics that can be made bacteria free.


The Division of Pharmacology makes biological assays of drugs and toxicological studies. This division works closely with the research staffs connected with the United States Pharmacopoeia, the National Formulary, and the Homeopathic Pharmacopoeia.

The Microanalytical Division concerns itself with microscopic identification of constituent ingredients of various mixtures, as well as the detection of decomposition and filth in foods, drugs, and cosmetics. By laboratory examination of samples prepared under practical commercial conditions, it is possible to determine whether any particular product submitted meets with the standard of purity set up for the protection of the consumer.10

Co-operation with State and Local Officials.

The FDA has a Division of State Co-operation for the purpose of exchanging local, state, and federal information and more complete enforcement of the laws through all the jurisdictions.11

Collaboration with other Departments.

The Food and Drug Administration gives technical assistance for non-regulatory purposes to the Veterans Administration; the Panama Railroad; and the Departments of Interior, Treasury, War, and Justice. The FDA advises

10 Ibid., pp. 4-6.
11 Ibid., p. 6.
these respective departments on the relative value of products submitted by bidders, and whether contractors are complying with the specifications under which the goods were purchased by the departments.\(^{12}\)

A government bureau having as many divisions and varied responsibilities as the Food and Drug Administration would appear to be a relatively expensive arm of the government. However, if credence can be given to the following references in such fiscal matters, the contrary must be the case.

The Administration, with a staff of around 900, operates on a modest appropriation of two and a half million.\(^{13}\)

Concerning the Administration's ability to make a little go a long way, one writer observes:

To protect the nation's supply of foods, drugs and cosmetics, valued at twenty billion dollars, Congress gave the Food and Drug Administration an appropriation of $2,128,000 for the year ending June 30, 1944. ... Campbell's technic for getting the job done - for stretching the taxpayer's dollar - rests on the belief that the overwhelming majority of food, drug and cosmetic manufacturers are anxious to obey the law.\(^{14}\)

Another writer comments:

... This is just one example of what this government bureau with a budget of less than three million dollars (admittedly peanuts these days) and a staff of only eight hundred and fifty for the entire country -


\(^{13}\) "New Drug Act in Full Effect July 1," \textit{Business Week}, p. 50, (June 29, 1940).

administrators, chemists, laboratory technicians, inspectors and secretaries - is doing to save not only your pocket-book but your life. ... 15

In commenting on the retirement of Walter G. Campbell, as Commissioner of the Food, Drug, and Cosmetic Administration, an experienced Washington correspondent wrote:

Campbell's retirement from public service has robbed the government of its number one "model bureaucrat". ... One principle dominated Campbell's years of government service - the taxpayer must get full value for every dollar spent. ... The story of the Food and Drug Administration as it stands today is Campbell's monument. ... To detect food, drug, and cosmetic adulterations and mis-brandings, Campbell developed a small but effective corps of inspectors who are the equal of J. Edgar Hoover's more widely publicized G-men or the Treasury Department's secret service agents. ... 16

We have a close-knit government bureau that is flexible in operation, working for the common good of the public, whether producer, handler, or consumer.

15 Rita Halle Kleeman, "Food and Drug Cop," Collier's, CXVI, 23, (Sept. 1, 1945).

CHAPTER IV

IMPORTANT SUB-DIVISIONS OF THE LAW

AND THEIR APPLICATION

The particular law that this paper deals with has definitions, standards, and regulations within the law itself. This chapter will list the most prominent ones. No attempt will be made here at interpretation, for that is the function of our Federal Judiciary and is taken up in Chapter V. This law naturally affects certain individuals and organized groups, adversely or otherwise, so the reactions of some of those affected will be mentioned.

Regulations and Hearings.

The Act itself in the chapter entitled "General Administrative Provisions" provides for the promulgation of regulations for and standards of identity of those articles covered by the Act. Section 701, paragraphs (e) and (f), (see insert, back cover) shows the considerable authority of the Administrator. The Administrator's promulgated regulations and standards have the force of law and can only be set aside by a decision of the Circuit Court of Appeals of the United States.1 It is little wonder then that all interested parties generally put in an appearance whenever the Administrator announces a hearing for the purpose of making a change

1 "Federal Food, Drug and Cosmetic Act and General Regulations for its Enforcement," Food, Drug, and Cosmetic No. 1 Revision 1, 3-5.
in, or issuing new regulations or standards of identity.  

Cosmetics.

The field of cosmetics came under federal regulation for the first time after the passage of the present law in 1938. The necessity for so doing is well illustrated by the following excerpts taken from the January 1940 issue of the magazine published by the National Federation of Business and Professional Women.

Beautification in the United States has become Big Business. Within forty years, the annual production of American cosmetics has increased from less than $7,000,000 to more than $20,000,000, and in addition, last year almost another $200,000,000 worth of American toilet articles was sold. Total retail sales of perfumes and cosmetics for 1938 were estimated at $364,000,000 and sixty thousand beauty shops do a yearly business of more than $100,000,000. ...

Why has the government found it necessary to concern itself with the creams, lipsticks, hair tonics and dyes, bath preparations, deodorants, depilatories, soaps and powders with which you attempt to keep yourself youthful, lovely, and sweet-scented. Pay a visit to the Food and Drug Administration's Museum — often called the Chamber of Horrors — at the Department of Agriculture, in Washington, and you'll find the answer.  

It is in the interest of consumers and manufacturers that legal controls be set up to guarantee the safety and purity of cosmetics. We know that the public has been shamefully taken advantage of when they had no means of


knowing what the cosmetics contained in the past.4

New Drugs.

Cosmetics was not the only new field covered in the Act of 1938. "New drugs" is not only a new field to be covered by the Act, but it was not even thought of in the earlier proposed laws to revise the (Wiley) law of 1906. This is one section of the present law that can be directly attributable to the "elixir sulfanilamide" tragedy of 1937, previously mentioned in Chapter I. When the reason for the tragedy was learned the Secretary of Agriculture recommended, among other things, that legislation be enacted to provide for the license control of new drugs to insure that they will be safe for use before retail distribution.5 This was done by the inclusion of Sections 301 and 505 with their effective subsidiary paragraphs.6

Today it is necessary for the manufacturer to fill out a comprehensive application and submit samples of his proposed product in the manner he intends them for commercial use.7

Imported drugs are subject to the "new drug" section,

4 Ibid.
6 Ibid., pp. 72-75.
7 Ibid., p. 81.
and the Secretary of the Treasury is directed to refuse admission to any article in violation of Section 505.8

Some manufacturers of "new drugs", in their anxiety to make money, still do not carry on enough investigations and experiments to create a product that is truly beneficial to the public.

... Applications for such products are being submitted with greater frequency. The appraisal of the evidence relating to the safety of such drugs is becoming more complex and requires frequent consultations with experts in all fields of medicine. Unfortunately, in the rush to market new products many firms are content to do a minimum amount of investigational work with the result that the data accompanying the new drug applications for these products are in many cases wholly inadequate to demonstrate their safety for use.9

**Food Standards.**

The 1938 Act has many specific food provisions. In Sections 403 and 405 of the present law the Administrator is given authority to set up minimum standards of quality for food. He does this through his regulatory power granted him in the Act. To assist him in such technical matters a Food Standards Committee has been created. The precedent for a food standards committee predates both of the Pure Food and Drug Laws, going back as far as 1897.

There is one distinct difference between the old committees

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8 Ibid., p. 63.

and the ones since 1938; the older ones were experimental and advisory, whereas the present one is experimental, investigational, and has the force of law in its pronouncements.10

The Food Standards Committee is made up of representatives from the Association of Official Agricultural Chemists, the Association of Dairy, Food and Drug Officials of the United States, and the U. S. Department of Agriculture. Following public hearings, it is the duty of this committee to recommend definitions and standards to the Administrator for him to promulgate.11

Food standards must meet rigorous tests. A listing of the common characteristics of a product constitutes a standard of identity. Once the standard of identity has been fixed, no deviation is permitted the producer.12

Upon the basis of evidence recorded at hearings, standards of quality and fill are determined by color, size, texture, quantity, and freedom from defects.13

Before standards were set up, dishonest competition was more prevalent.14

10 "Food Standards Committee of the Food and Drug Administration," Science, LXXVIII, 234-235, (Sept. 9, 1938).
11 Ibid.
12 Ibid., p. 235.
13 Ibid.
14 Ibid.
Examples of the value of food standards are offered because of the extreme importance of food to the consumer. A food is defined as adulterated if, among other things, any substance has been mixed or packed with it so as to reduce its quality or strength, or if any substance has been substituted wholly or in part therefor.\textsuperscript{15}

Bread, for example, may be made with widely varying moisture limits and because of this, it is necessary to determine at what point water is being sold for bread. Tomato juice is defined as the unconcentrated strained liquid extracted from mature red or reddish tomatoes with or without scalding, followed by draining. The liquid may be homogenized and may be seasoned with salt.\textsuperscript{16}

Honesty and fair dealing require that canned cherries must state upon the label "Below Standard in Quality - Thin Fleshed" or "Blemished", or the statement "Below Standard in Quality - Good Food - Not High Grade." Where the standard or fill of container is not met, the label must state "Below Standard in Fill."\textsuperscript{17}

Businessmen sometimes try to use the Act as a competitive advantage to themselves. Segments within industries affected by promulgated standards can become quarrelsome with one another, generally at the eventual expense of the consuming public. Reported Business Week:

Of all the products that have suffered from state trade-barrier legislation, none has been so pushed around as oleomargarine. ... Right now, the dairymen are on the warpath again. ... Dairymen charge

\textsuperscript{15} "Food Standards," Food and Drug Administration, Miscellaneous Publication, No. 1, 10.

\textsuperscript{16} Ibid., pp. 10-11.

\textsuperscript{17} Ibid., p. 21.
that the regulations governing the vitaminization, artificial flavoring and coloring of oleomargarine will allow it to pass itself off as butter; they threaten resort to the courts to keep the regulations from becoming effective. Margarine producers counter with the statement that, with the exception of the provision for vitamin enrichment, there is nothing new in the regulations - there are no state or federal laws forbidding the artificial coloring and flavoring of margarine, though taxes often make it prohibitive - and that the FDA is merely setting up a standard.\(^\text{18}\)

The dairymen made good their threat to go to court, and, as is typical in all cases involving promulgated regulations or standards, that means the Federal Circuit Court of Appeals. The oleomargarine standard was affirmed by the court.\(^\text{19}\)

Industry is forever on the alert. In July 1940 a definition and standard of identity was promulgated to require that a product be designated by its common and usual name, "dried skim milk." The manufacturers of the product were not ready to accept such a standard and were willing to go to extreme measures to get it changed or repudiated.

Failing to win out in the Circuit Court of Appeals, they got a Congressional Committee to find that the term "dried skim milk" was unduly derogatory, and that "milk


\(^{19}\) "Food Standards," \textit{Annual Reports, Food and Drug Administration, 1941-1942, 1942-1943}, pp. 7-8.
solids not over 1½% fat" was quite all right. The bills were opposed by the Department of Agriculture, consumer organizations, and the Food and Drug Administration, because the proposed names would be confusing and misleading. Regardless, the bills became law on March 2, 1944.20

Once the law permitted the Food and Drug Administration to set up standards that were no longer advisory, but must be obeyed until changed, the Commissioner and his aides evolved a definite program that was gradually to become effective over a period of years. World War II, however, interfered with portions of it, and as food items became more scarce, parts of the program had to be abandoned altogether for the duration of the war. However, following the termination of hostilities the Administration picked up the loose ends where it left off and has been very active of recent date in furthering its original food standard program in the health interests of the eating public.21

By mid-year 1945 the Food Standards Committee was once again functioning for the purpose for which it was created.22

Vitamins.

The subject of vitamins, for most laymen, is not

22 "The Food Standards Committee of the Food and Drug Administration," Science, CI, 553-554, (June 1, 1945).
thoroughly understood. Experts, employed by the various producers of vitamins, endeavor to convey the impression that the vitamin of a particular label is the proper vitamin for you. Here is one place indeed where the absence of authority over food and drug advertising by the Food and Drug Administration is most unfortunate. Those responsible for the administering of the law do what they can in promulgating regulations, setting up standards, and enforcing labeling provisions of the law in an effort to help those persons who earnestly seek health solutions over the retail drug and food counters.

The Chief of the Vitamin Division of the Food and Drug Administration speaks:

... Protein is an important constituent of all living things. Muscle tissue and some other body structures consist chiefly of protein. ... It is only necessary to adjust the diet so that an intake of protein of sufficient quantity and of suitable quality is assured. ... It is difficult to understand the basis of current activity in the manufacture and promotion of products designed to supply amino acids. ... The distribution of preparations containing a mixture of a few of the amino acids with a mixture of some of the vitamins does not appear to be based upon any established need. ...23

The manufacture and selling of vitamins continues to be big business. Business men frequently quarrel with each other when they feel their special "lines" are being

infringed upon.

Various large grocery and drug concerns have fought each other frequently in the courts to gain an exclusive right to sell vitamin products to the public. 24

A glance at any grocer's shelves today will show one that the druggists lost out on his "vitamin monopoly." Both organizations do a large business in the selling of vitamins.

The vitamin testing program of the Vitamin Division of the Food and Drug Administration occupies a major portion of the working time of the Division. Most of the cod-liver oil used in this country is of foreign origin, therefore it is more practical to conduct the examinations at the port of entry. During the fiscal year 1936-1937 the Administration's figures show that 32 per cent of the volume of the oil examined was refused entry. The oil, if it would have been up to standard quality, could have produced enough vitamin D for more than 100,000 tons of poultry feed. 25

During the next fiscal year (1937-1938) laudable improvement in foreign cod-liver oil took place. Only 4.4 per cent of the volume of oil examined failed to meet the


standard for vitamin D.26

In the fiscal year 1938-1939 out of 945,482 gallons in 199 shipments of foreign cod-liver oil only 2.8 per cent was refused entry. When 95 follow-up interstate assays were made of some of this cod-liver oil, 12 were found to be deficient in vitamin D. "These investigations have revealed that in some instances higher claims are being made for certain interstate shipments of cod-liver oil than were made for the same oil at the time of importation. In each instance these higher claims were found to be unwarranted." The complete protection of the purchaser is not provided by examination of cod-liver oils at the port of entry only.27

As the roar of World War II increased and expanded in operation, its pronounced effect was felt in vitamin circles. According to the official report of the Food and Drug Administration:

The situation with respect to cod-liver oil imports was abnormal because of the outbreak of the war in Europe early last fall. Normally more than one-half of the cod-liver oil imported originates in Norway and England. The latter country put an embargo on the exportation of cod-liver oil shortly after the war began. Two tank boats, each carrying about one-half million gallons of oil, were entered in August. Unusually heavy importations from Norway followed during the next few months, but shipments declined rapidly shortly after the


first of the calendar year and since that time have been far below normal. The quality of oil offered for entry during the year was quite satisfactory, the percentage of rejections being 0.6 in 1940. ...

The Vitamin Division examined 192 samples of imported cod-liver oil, representing 2,420,116 gallons, an increase in volume over the 945,482 gallons examined last year.28

The following would indicate the change in technique in the work of the Vitamin Division after our own country was directly engaged in war:

The fiscal year 1942 marked the beginning of the extensive use of microbiological and chemical methods for vitamin determinations. These methods require less extensive equipment and only a fraction of the time necessary for bioassays. While chemical methods had been used in the past for determination of vitamin A and vitamin C, they can now be applied also to many products being tested for vitamin B1. Chemical methods for niacin, however, have only limited application and microbiological tests are used extensively. The only vitamin for which biological assays must be depended upon completely is vitamin D.29

Labeling.

It could be said, with some justification, that the Food and Drug Administration is in an unusual position. For all the good it is capable of doing, and does do, in spite of its handicaps mostly as a result of limiting legislation, the Administration's one big opportunity to reach the consuming public it is everlastingly trying to protect and


29 "Vitamin Products," Annual Reports, Food and Drug Administration, 1941-1942, 1942-1943, pp. 45-46.
enlighten, is through its "labeling provisions."

The writer is aware of the fact that on occasion officers of the FDA get informative articles published in trade magazines, and less frequently in magazines of general circulation; that representatives of the FDA occasionally appear before conventions of manufacturing and producing organizations, and even are welcome guest speakers before established consumer groups. On the rarest of occasions does the FDA make the news columns of metropolitan dailies, though FDA does issue press releases in an effort to educate the public to understand the Administration's problems and ask for co-operation. Newspapers seem to be interested only at times like the sulfanilamide scare, and then only transiently. The FDA is specifically prevented by law from supervision of newspaper, magazine or radio advertising of those products that otherwise fall within its scope. Thus, by and large, the only practical method FDA possesses for reaching the 140 millions that make up the buying public in this country is through understandable labeling of the products over which they have jurisdiction. And FDA bends every effort to make a maximum use of that power.

One of the major bones of contention during the five year Congressional fight to enact the present law was the provision governing labeling. Very little in the law itself refers to labels and labeling, so that FDA has had to
make itself effective in an indirect way or through its powers of promulgating regulations, which are specific and binding until upset by court decisions, or set aside by the Administration itself.

It appears from the material available that all interested parties swung into action over the problem of labeling as soon as the present law was enacted.

By reason of present regulations, that part of the label customarily displayed to the consumer must have all the labeling information on it required by the law. Commented Business Week:

(This) ought to raise merry nead with the manufacturers who have trick, octagonal bottles, or the manufacturers of fancy perfumes whose sales are made because the bottles look so pretty and uninformative. These are the regulations currently causing the greatest concern to the food, drug, and cosmetic industries.

With a new law about to go into effect the Food and Drug Administrator held public hearings on its regulatory provisions, as a courtesy and as a way of informing the food, drug, cosmetic, and device industries what to anticipate.

The hearings were held in November, and on Christmas Eve of 1938 the regulations that evolved from the previous


31 Ibid.
hearings were made public. The first result was confusion.32 One writer predicted that:

Hardly a food, drug, or cosmetic product, or a "device", subject to the act, will be able to go forth in its present dress without running afoul of one of Chief Inspector George P. Larrick's field men who will be on the lookout for violations. Consequently, new labels, new printed literature (defined as "labeling" in the law), new containers will be required in immense quantities.33

The most controversial provisions of the tentative regulations have been eased up. The first of these, under the tentative regulations would have subjected producers to a misbranding charge if there was a difference of expert opinion as to representations made on labels and if the labels failed to bear statements of the existence of this difference. This provision was changed to require difference-of-opinion statements only when representations are made which are contrary to the "material weight" of expert opinion.34

Second and most highly controversial provisions would have compelled manufacturers to place on all panels of a package all information required by the law. Roars of protest greeted this proposal, and it has been changed merely to require as much information as possible on the front panel.35

Manufacturers are left to decide for themselves what information to place on their front panels. Instead of stating definitely what must appear on labels, the regulations say merely that products may be considered misbranded if labels fail to carry certain information.36

33 Ibid.
34 Ibid.
35 Ibid.
36 Ibid.
Heartbreaking as it may be, the regulations leave no doubt that manufacturers will have to discard beautiful and fancy labels in favor of those carrying the prosaic information required by law, such as quantity, directions for use, names of ingredients. Space heretofore given over to promotion, manufacturer's name, vignettes, and designs will have to make way for straight stuff.

Trick type is out, as are color combinations which render printed legends inconspicuous. Tiny labels on large bottles will not be accepted by FDA as an excuse that there is no space for information required by law. Labels will have to be enlarged even though they may cover all of once beautiful bottles. Containers themselves will come in for changes if they are of such shape as to deceive the consumer.37

In the last year the Act of 1906 was in full force the Chief of the Food and Drug Administration called particular attention to the following two instances, among others, illustrating what the public is up against when a product is mislabeled.

One product consisting of nitro-glycerin tablets intended for hypodermic use, and labeled as containing not over one-hundredth of a grain of nitro-glycerin, upon analysis showed a shortage of approximately 86 per cent of the medicinal ingredients. Investigation developed that the manufacturer was using ordinary dynamite instead of nitro-glycerin purified for drug purposes. For this he was fined $250 and costs.38

37 Ibid.
In another case involving 25 samples of a manufacturer's ampuls there was a variation in the potent ingredient ranging from a shortage of 82 per cent to an excess of 175 per cent in the samples as labeled.39 Hardly protection for the consumer.

As we already know, an obliging Congress postponed for more than a year many of the provisions of the present act; yet as late as March 25, 1939, we find an article that reveals the attitude of many toward correcting known abuses in the food and drug line.

Effective date for the Food, Drug, and Cosmetic Act is only three months away, yet time-extension requests that are pouring into Washington make it apparent that scores of manufacturers and distributors have not yet finally made up their minds just how they are going to comply with labeling provisions. Thus far Washington has evidenced no disposition to extend the period of grace. With manufacturers and printers of packages and labels likely to be swamped with last minute orders, some food, drug and cosmetic companies are going to be caught short when the June 25 date rolls around. ...40

During this same period industry seems to have found time for a little internecine warfare in labeling as well as opposing the government in the same field.

Two wealthy and powerful business antagonists, the corn and sugar cane interests, had a series of quarrels over

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39 Ibid.

whether the word "dextrose" had to be used, or could be omitted in the labeling of canned fruits and vegetables. Corn people did not want dextrose to appear, sugar cane interests insisted on its appearance as a corn derivative on the label. The FDA is in favor of the compulsory label declaration of dextrose on the ground that the buyer is entitled to know what is in the product he purchases. A number of wrathy hearings were held with scientists extolling the virtues of corn derivatives and sugar cane. In the end the position of the Administration prevailed.41

Simultaneously the following was taking place in Congress itself, and has the appearance of pressure lobbying activities.

In the House of Representatives, manufacturers won a year's reprieve from most of the labeling provisions. The Senate granted an additional six months' grace, or until July 1, 1940, to any manufacturer that filed an affidavit with the Secretary of Agriculture stating that compliance would be "unduly burdensome" and that the public interest was "being adequately served". The more liberal Senate proposal prevailed.42

These are the items that do not have to be declared on

41 "Big Corn, Cane Fight," Business Week, p. 36, (April 29, 1939).

labels until after July 1, 1940: the name of packer or distrib-  

tributor; the name and proportion of each ingredient; arti-

tificial coloring or flavoring; failure to meet standards  
of quality and fill of container; and amount of vitamin and  

mineral content in special dietary foods.  

The same sort of generosity was extended to cosmetic and  

drug manufacturers, even to postponing the acknowledg-
ing of each one of seventeen habit-forming drugs on the la-

bel.  

A reaction to all this generosity:  

Food and drug officials make no bones about their  

disappointment over the extension, but they have  

found some balm in Gilead. As one cryptically put  
it: "We'll at least get a complete list of all  

the food, drug, and cosmetic manufacturers as a re-

sult of that Senate amendment granting an extra six  

months' grace simply on presentation of an affi-

davit."  

The problem of labeling possesses a wide interest as  
demonstrated by having such a speaker as Ole Salthe, consul-
tant to the Food and Drug Administration, speaking on "La-

beling Requirements of the Food, Drug, and Cosmetic Act",  
at a convention of the Lithographers National Association  
held at Rye, N. Y., in the early summer of 1939.  

He  

43 Ibid.  

44 Ibid.  

45 Ibid.  

46 "Symposium on Foods and Drugs," Canning Age, XX, 319,  
(July 1939).
endeavored to demonstrate the method of approach to the labeling problem on the part of the FDA.

Salthe claimed that the FDA makes every effort to assist the manufacturer in interpreting the law and the regulations. The burden of revision of labels will be passed on to the label manufacturers. Congress is now asking the packer to tell the consumer the whole facts and nothing but the facts about his product. Labeling may be false or misleading not only because of what is said, but also because of what the manufacturer fails to say. A label may be misleading by reason of the order, or relative prominence of the names of the ingredients. Mr. Salthe concluded by urging approach to the law in the spirit of co-operation and understanding.47

The FDA, always vigilant, shows a keen interest in the most recent industry under its jurisdiction.

... The FDA will conduct a widespread survey of the cosmetics industry to see if it is complying with the label principles laid down in a trade letter issued by FDA Chief W. C. Campbell in August. That letter announced that the FDA regarded as false and misleading, because of the impossibility of fulfilling implicit promises, certain cosmetic names and label statements based thereon. Some of these names were: eyelash grower, rejuvenating cream, skin tonic, wrinkle eradicator, muscle oil, and circulating cream. This work will take up the FDA's time during

47 Ibid., pp. 519-520.
December. 48

We will conclude the year 1939 on the subject of labeling with some unusual comment from the annual report of that year.

One proprietary product made the subject of six uncontested seizures deserves particular mention. It consisted essentially of aminopyrine, hydroxyquinoline sulfonate, and salicylic ethyl ester carbonate. The article was labeled with a fanciful name followed by a complicated chemical name, "aminodimethylpyrazolon-quinolinesulphonate", which purported to identify the ingredients. No lay user and probably few chemists or physicians would recognize that the first member of this hyphenated name is a chemical synonym for aminopyrine, a drug that has wrecked the health of many users. The label was highly deceptive in that the name used ignored the presence of the salicylic acid compound in the drug and deliberately concealed the presence of the dangerous ingredient, aminopyrine. 49

The corn, sugar cane interests, and the government are not the only ones that engage in three-way jousts on occasion. The non-proprietary and the proprietary drug and medical manufacturers were each trying to force the FDA into announcing types of warning labels that were harmless to business, or allow manufacturers to compose their own. By watchful waiting while the tempest was on, and the strategic timing of announcing what labels the FDA considered legal

proved to be satisfactory to all parties concerned.50

Vitamins are not neglected either in the manner of labeling, as witness:

Last week a long-awaited bombshell was dropped on the U. S. vitamin industry. It was aimed by the Food and Drug Administration, which set up tentative regulations concerning vitamins A to G. ... The joker, which is going to cause the major part of the shouting, comes in one sentence, requiring flatly that the labels of all foods making Vitamin D claims carry the statement: "When the skin is adequately exposed to direct sunshine there is no established need for vitamin D in the diet." This if it goes through will pare down the biggest slice of the fat vitamin pie-sales of the long-established and eminently marketable D, the "sunshine" vitamin. ...51

... In the past ten years there has grown up in America what amounts to a vitamin cult. ... Today a good sized metropolitan drug store stocks around 500 separate vitamin products.52

"Supplying the country with its A, B, C's is an industry as complex as the vitamins it sells." Besides the regular pharmaceutical houses, such diverse firms as Eastman Kodak, General Mills, Atlantic Coast, Bothe, and Gordon-Pew Fisheries, Merck, Standard Brands, and the Borden Company are all interested in making sure that each individual is supplied with a daily share of vitamins.53


52 Ibid.

53 Ibid., pp. 40-43.
Reported Business Week:

Just how big sales of concentrates and vitamin impregnated foods are annually is not known. A fair estimate, however, is that drug marketed $50,000,000 worth of vitamin products last year (1939) — around 4% of their total sales. Sales of vitamin-impregnated food — marketed mainly via grocery stores — probably surpass this figure. Vitamin concentrates and vitaminized cosmetics also move across department store counters (pioneer here was Vitamin Plus) and are distributed by mail. And that doesn’t take into consideration the tremendous sales of vitaminized food for animals and plants. Practically every chick in the country gets its daily ration of vitamin D, and B1 tablets are on the market for the well-cared for garden.54

The big names in the vitamin business will be glad that the Food and Drug Administration stepped in and regulated the industry. In this highly competitive business, industry regulation has been notably unsuccessful in the past.55

As one commentator noted:

What small measure of control there has been, has been exercised by the American Medical Association which has consistently decried wholesale fortification of foods, drugs, and cosmetics, pointing out that the average individual gets all the vitamins he needs from a well balanced diet, and that cases of real deficiency usually exist among those too poor to afford special drugs and vitaminized products. ...56

Advertising and labeling got mixed up interchangeably at another hearing. Defining the problem, one writer

54 Ibid., p. 41.
55 Ibid., pp. 42-43.
56 Ibid.
commented that if the Food and Drug Administration has its way, a food advertiser who boasts about the vitamin or mineral content or dietary values of his product will have to state the scientific basis for such claims on the label of his goods.57

Here is where the advertising angle comes in. Determining whether a product must be labeled according to the stringent special requirements depends on the claims made in advertising or labeling. That means that the copywriter, who hitherto has had to keep his eye only on a comparatively inactive Federal Trade Commission, will also have to watch out for a hard-hitting FDA, if the rules go through.58

The "battle" of the various vitamin interests resolved itself into a long and hectic one despite the previously stated hope that after the "tumult and shouting are over the vitamin industry will be glad the FDA stepped in."

During 1941 we find that a Dr. Russell Wilder, Mayo Clinic physician and active advocate of the use of vitamins, appealed direct to Federal Security Agency Administrator Paul V. McNutt to curtail the regulation of vitamins and minerals by the FDA, claiming that the agency was exceeding its legal authority.59

There were some disturbing thoughts on the part of


58 Ibid.

nutritionists that sponsors would stop their expensive enrichment promotion campaigns.60

Dr. Wilder's committee, knowing that the Food and Drug Administration was preparing formal regulations and standards covering the entire enrichment field, published their own in January 1941, and issued them again at the National Nutrition Conference in May of the same year. This seemed to be assuming a lot of authority and responsibility for such a person as the good doctor.61

Dr. Wilder doesn't have any official government position. ... (He) serves as the spearhead of a group of nutritionists who have gone all out for vitamin B1 - so much so, they have irreverently been called "the vitamin B1 boys". This group believes that the U. S. diet is grossly deficient in B1, the so-called nerve and morale vitamin. ...62

On the other side of the controversy, the FDA indicates they have no intention of hampering the nutrition program, nor do they seek to be in the nutrition spotlight; all they are trying to do is enforce the law regarding dietary labeling requirements. The chief of the FDA points out that every period of national emergency brings forth its nutritional enthusiasts who want to save the country with their pet dietary theories. He further points out that his

60 Ibid.
61 Ibid.
62 Ibid.
agency and the national nutrition program have the same goal, that of educating the consumer. Mr. Campbell asks, "what better means of educating the consumer can be found than use of the label to tell all about the food?"

On May 18, 1942, the Food and Drug Administration issued its new vitamin and mineral content regulations. Few people outside the food and drug industries know how much ground this covers. The list includes such things as vitamin and mineral capsules, concentrates, tablets, and liquids; all fortified or enriched foods, including enriched bread, flour, oleomargarine, breakfast cereals, and even candy; the so-called "health foods" and all infant foods and products especially prepared for diabetics, pregnant or lactating women, and people suffering from allergies, overweight or underweight conditions.

The pharmaceutical industry still tried to get FDA to exclude from these latest regulations vitamin and mineral preparations in doctor's prescriptions. They failed in their purpose.

The drug industry as a whole co-operated with the Administration in changing and correcting its labels to meet

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63 Ibid.
64 "Vitamin on Label," Business Week, p. 49, (May 16, 1942).
65 Ibid.
the requirements of the new law and new regulations. Particular correction took place in the labeling of headache remedies.

Effective June 25, 1939, was the enforcement of the prohibition against misbranding of devices with false and misleading claims. The chief of the Food and Drug Administration reported:

The largest number involved therapeutic lamps, heat and light applicators, and other devices incorporating an electrical impulse; they bore claims for such serious disorders as kidney and heart disease, eczema, abscesses, gangrene, varicose veins, asthma, ulcers, rheumatism, and in some cases even Bright's disease and diabetes. Next in number were vaporizers and inhalers, which stressed respiratory ailments in particular, but did not confine themselves to so limited a field.

During the year 1940 various canners throughout the United States had voluntarily taken on the "U. S. Grade A-B-C" inspection service offered by the Agricultural Marketing Service of the Department of Agriculture. Once the canned goods have passed inspection of this particular government bureau, the labels of the cans have the right, given by the Department of Agriculture, to state "U. S. Grade A", U. S. Grade B", or "U. S. Grade C". By April 1941 this grading

66 "Actions on Drugs and Devices," Report of the Chief of the Food and Drug Administration, 1940, p. 16.
67 Ibid., p. 17.
procedure came to the official notice of the Food and Drug Administration, which by this date was no longer a division of the Department of Agriculture. Reported Business Week:

The Federal Food and Drug Administration which has the job of enforcing truthfulness on labels of all food products, recently let out that it is a factor to be taken into consideration in the trend toward grading.68

The trade has long expected the Food and Drug Administration to launch a check up on the scrupulousness with which these goods are labeled and at last, FDA has begun seizing cans for a few test cases. ... It's no secret that FDA regarded BAE grades virtually unenforceable as long as flavor was one of the factors in the grades. Now that flavor has been eliminated, FDA apparently feels that they can be made to stand up in court.69

Apparently FDA was welcoming a friendly court test on whether Agricultural Marketing Service A-B-C grades and "Fancy" grade could be established as legal bona fide grades. To this end FDA made nearly 50 seizures of canned goods belonging to American Stores Co., a large Philadelphia grocery chain, and a like number of seizures of canned goods of the Great Atlantic and Pacific Tea Co. The Ladoga Canning Co. of Indianapolis which packs corn for those large chains seemed to be just as anxious for a court test as the Administration. After a number of legal feints, surveys and statements from the interested parties court action was


69 "Is It A-B-C?" Business Week, pp. 59-61, (April 19, 1941).
dropped by mutual consent. All parties concerned are right back where they started before the seizures took place, with nothing decided.\textsuperscript{70}

The year 1941 was an eventful one in the activities of the Food and Drug Administration in many ways. Herewith is another phase of its alertness and authority.

Owners of patents and trademarks had something new to worry about—proposed regulations of the Food and Drug Administration which would declare several valuable and important trademarks in the pharmaceutical field to be "common or usual" names. The U. S. Trade Mark Association was sufficiently exercised to file a brief contending that the FDA action constitutes a danger to all trademark rights.\textsuperscript{71}

Under the existing law, the Federal Security Administrator is empowered to designate all derivatives of barbituric acid and other narcotic and hypnotic substances which are habit forming. Big pharmaceutical names, such as Winthrop, Squibb, Eli Lilly, Sharpe and Dome, and Park, Davis have popular trademark products they do not want to see jeopardized.

Another section in the same law says that a drug must


\textsuperscript{71} "Trademark Threat," \textit{Business Week}, p. 60, (May 17, 1941).
be labeled by its common or usual name. As patents expire, competing companies could put out the same product using the trademark name as its own. Food and Drug's defense is that they have a law whose provisions must be enforced. 72

Controversial issues are frequently compromised during administrative hearings. The pharmaceutical industry feels it has gained a victory, shown as follows:

... In short, this is how things stand now. Whereas the original FDA regulation would have declared "phenobarbital" to be in fact, a common name, the regulation now merely says that "phenobarbital" must be labeled by its common name. The hairline difference, in effect, hinges on the difference between the concept "is a common name" and the concept "must be labeled by its common name." A flat, formal administrative declaration which might affect the ownership of trademarks is thus avoided. ... 73

Even the entry of the United States into World War II did not abate the efforts of the Food and Drug Administration to enforce higher standards of labeling. Reported the Administrator:

Proprietary remedies for human use seized for false and misleading claims in 1942 and 1943 include laxatives, tonics, and mineral waters bearing claims for the treatment of constipation, hyperacidity, or other digestive disturbances; products labeled as effective in the cure or treatment of venereal diseases; vitamin or mineral preparations represented as supplying the body's need for energy and vitality; alleged treatments for colds, grippe, and various other respiratory diseases; products recommended

72 Ibid., pp. 60-61.
for women's disorders; and medicines for the treatment of arthritis and other pains of the joints and of muscles. Seized in smaller numbers were dentifrices, hair tonics and restoratives for gray hair; alleged diabetes remedies, treatments for high and low blood pressure (at times in the same bottle), preparations for the skin, eye and ear ointments and antiseptics. In addition to these there were many general nostrums not limited to any single class of disorders. Other preparations seized for false and misleading claims were a number of so-called weight reducers depending upon laxatives or diet prescribed in the labeling to achieve the promised results.74

Again the Administrator reported:

The increased purchasing power of many consumers, together with a shortage of civilian physicians particularly in congested war industry localities, apparently has given an impetus to the sale of proprietary remedies, and to vitamin and mineral products for real or imaginary dietary deficiencies. The Administration has been unrelenting in its efforts to protect the consumer from being victimized by the promoters of so-called remedies ill-suited for the conditions for which they are sold. The fiscal year brought the highest number of seizures and prosecutions for misbranding with false and misleading claims since the enactment of the 1938 law. It is encouraging to report, however, that 1944 court actions involved the lowest percentage ever encountered in the history of drug law enforcement of products claiming the cure or alleviation of serious diseases of the type that would become difficult or impossible to cure if competent medical treatment were delayed.75

In respect to therapeutic claims regarding tonics and products containing vitamins and minerals this is an interesting commentary:

While most of these preparations do not directly

74 "Misbranded Drugs," Annual Reports, Food and Drug Administration, 1941-1942, 1942-1943, p. 40.

75 "Misbranded Drugs," Annual Report, Food and Drug Administration, 1944, p. 58.
affect the consumer's health, their false insinuations of the inadequacy of the normal diet to supply him with the nutritional elements he requires have been a rank exploitation of his eagerness to benefit from true scientific progress in the field. 76

The next year's report states:

There are, in addition, many manufacturers, both new and old, who are careful to keep the claims on the package label within the limitations of the Act, but who make unwarranted claims in circulars and other promotional material. 77

Concerning the value of full and accurate labels, a woman's magazine advises:

Canned fruits pay just as husky dividends to the label-readers as do canned vegetables. ... Decide what you want, read the label, and know what you're getting. ... The more detailed and understandable their information - as to color, texture or maturity of the product, as to size and number of pieces, as to cups and weight and servings per can, as to seasoning and suggested uses - the better buying guides they are, and the better canned-food shopper you can become if you use them. ... 78

Inasmuch as diligent search has not uncovered any evidence of serious mislabeling of canned food products, it would appear that the canned food industry has a much cleaner record than the drug industry as far as violations of the Act under consideration is concerned.

It appears that the Food and Drug Administration endeavors to keep faith with the consuming public, and

76 Ibid., pp. 28-29.
78 Joan Guthrie, "Read the Label on the Can," Better Homes and Garden, XX, 46, (June 1942).
likewise be fair to the producers of articles under its jurisdiction.
The present chapter will discuss the enforcement activities of those Food and Drug Administration representatives who are authorized to make inspections, investigations, laboratory assays and arrests for violations of the Food, Drug, and Cosmetic Act. Whenever there are arrests for violations, court trials are a natural sequence. However, it must be borne in mind that the criminal cases, that evolve from enforcement work conducted by the inspectors, are not always the most important cases concerning the activities of the Administration. Equally important are the civil cases brought against the Food and Drug Administration by a producer or processor seeking to establish his legal rights in the component parts making up his product, or to modify some promulgated regulation. This chapter will attempt to give typical examples of both types of cases in addition to enforcement activities.

**Enforcement.**

In an interview with the author, Mr. Van W. Smart, legal officer attached to the San Francisco Station of the FDA, stated: "We are primarily in the warning business." He went on to emphasize that a warning to a violator more often than not brought about an early correction of the violation, that there was no need for an arrest, or preparation of a court case. One gathered the impression that most of those who,
by the very nature of their business, had to deal directly
with any officer or official of the Food and Drug Admin-
istration had a healthy respect for what the Administration
determined was right or wrong. Also, that most businesses
over which the Administration had jurisdiction are general-
ly willing to co-operate in the interest of the business
and the consuming public.

The field force attached to the Food and Drug Adminis-
tration didn't just happen, but rather followed an evolu-
tionary course in relationship to existing circumstances.

Thus, a bit of background would be apropos.

In the period since 1906, there has been greater
industrial expansion than had theretofore occurred
in all history. ... 1906 was the age of pro-
tein-fat-carbohydrate food value estimation; to-
day is the vitamin and amino-acid age. That may
be called the patent medicine age; this, the
vitamin chemico-therapy, anti-biotics age. This
is the package age, the delicatessen age - that
was the age of home production and bulk distribu-
tion. ... The value of annual commerce in the ar-
ticles under control has increased from a few
hundred millions to 25 billions. Products under
supervision have grown from about 100,000 to con-
siderably more than a million items. Firms and
individuals amenable to the terms of the Federal
Food, Drug, and Cosmetic law now number more than
100,000. From the comparatively small beginning
of the early part of the century, the growth of
these dimensions has been gradual with accelerated
speed in the last decade.¹

In 1907 there were 29 inspectors to cover the whole

¹ W. R. M. Wharton, "Its Inspection Evolution," Food-Drug-
Cosmetic Law Quarterly, 1, 356, (Sept. 1946).
United States. W. G. Campbell was the Chief Inspector, later Chief and Commissioner of the Administration. It was Campbell who realized the hopelessness of individual seizures and chemical examinations as far as effectiveness was concerned in protecting the public.\(^2\)

By the end of the first decade of the present century, Chief Inspector Campbell had influenced a change of procedure. The new system devised better to achieve consumer protection, was predicated upon the proposition that the detection of violation should be as nearly at the source of the violation as possible; that is, at the factory, mill, processing plant, or the producing area of the articles. \(^3\)

By 1914 still another move in improving enforcing methods, called the project system, took place, also under the leadership of Campbell. The theory being that matters of first importance in the eyes of the public should have first attention.

... violations of the law having adverse effect on health should receive first regulatory attention - illustrations: food containing poisonous ingredients, potent drugs dangerous to health when taken as directed, hygienic violations which affect the aesthetic sensibilities should be considered of next importance. Illustration: products which are filthy, decomposed, or putrid. (Some of these are also dangerous to health.) Third in the scale of importance: economic violations; i.e., those contributing major frauds. Technical and minor misbrandings of little public significance were to be ignored or corrected by correspondence. \(^4\)

\(^2\) Ibid., p. 357.
\(^3\) Ibid.
\(^4\) Ibid., p. 358.
The planned project system of operation, the integration of the inspection operations with those of the laboratories, the development of highly trained specialists in the technique of inspection of the most intricate and complicated processes of manufacture of foods and drugs had been accomplished when the Food, Drug, and Cosmetic Act of 1938 became effective. ... The 1938 law provided authority for federal inspectors to make factory inspections, an element of authority required for effective operations of the developed inspection system. 5

Certain individuals apparently will try to put anything on the market if it will sell. About three months before the present law was effective, twelve deaths resulted in Florida from the administration of an alleged cancer serum contaminated with tetanus toxin due to faulty manufacture. The FDA traced all remaining lots of the contaminated product and removed it from the market. This happened in spite of the "elixir" tragedy of a year previous. 6

About as soon as the FDA was legally empowered to do so, they seized in Atlanta, Georgia, and seven other cities, over 1,000 samples of Emerson's Bromo-Seltzer. The charge was that "they were dangerous to health when used in the dosage ... suggested in the labeling." 7

At the outset it looked like the government would have a tough job of proving that a product for which consumers spent $20,000,000 each year was dangerous under certain

5 Ibid., pp. 359–360.
6 Walter G. Campbell, "Drugs and Drug Traffic," 1939 Britannica Book of the Year, p. 216.
7 Edward R. Keyes, "Food and Drug Detectives," Reader's Digest, XXXV, 46, (July 1939).
The history of the Bromo-Seltzer case was shorter than anticipated. The manufacturers quietly dropped the acetanilid and bromide content to the point FDA accepts as legal. The result, no court case.9

The present law was only a month old when the government seized a product named

... Causalin, which bore the subsidiary label, "Aminodinmethylyrazolon-quinolinesulphonate." The press was amused that the 16-syllable designation wasn't enough. But the government was really objecting that the name concealed, rather than disclosed, the fact that this widely advertised rheumatism "cure" contained amino-pyrine, a pain-killer, sometimes deadly.10

However, routine inspections and seizures possibly do more to contribute to our better health and well being than the more "dramatic" cases. For example, during 1938, the following found its way to the dump heap after seizure by Food and Drug Inspectors: 2,600,000 lbs. of maple syrup contaminated with lead; 798,000 lbs. of worm infected Canadian whitefish; 3,700,000 lbs. of condiment seeds having insect and rodent excreta; 6,000,000 lbs. of insect infected dates; and 37 shipments of non-sterile surgical supplies.11

8 Ibid.


11 Ibid., pp. 48-49.
Two industries in particular require almost constant supervision; the apple grower for too much poisonous spray, and the crabmeat fisher because some operators haven't even elementary ideas of sanitation.12

Not all industries are so troublesome; for example, the bureau rarely worries about the purity of the fruit and vegetable canning industry. "Not one death has been caused by a commercially canned food product in the United States in the past nine or ten years."13

During the fiscal year 1938, the government spent only 1.1 cents per citizen to protect its population against the ever-present threat of poisonous foods and dangerous drugs.14

The American Home Economics Association, always interested in the protection of the consumer, offers a report of the activities of the Food and Drug Administration of particular interest to women. Excerpts follow:

... These beauty products included, in addition to eyelash dyes, such preparations as skin bleaches and freckle creams containing mercury compounds, a mole remover composed of acetic and nitric acids, lipsticks depending for their coloring properties on cadmium and selenium, and coal-tar hair dyes which failed to carry the required warning against possible injury. ... Another type of beautifier which was subjected to legal action was fat-reducing agents. The mere passage of the act was enough to

12 Ibid., p. 49.
13 Ibid.
14 Ibid., p. 50.
cause the death dealing, sight-destroying dinitrophenol preparations to vanish from the market like mist before the sun. ...  

A study of deceptive containers was begun during this period, resulting more recently in seizures of candy, spaghetti, tea, grated cheese, mustard seed, celery seed, pretzels, face powder, deodorants, and practically every brand of 10-cent tooth paste because their packages were so made, formed, and filled as to deceive the consumer.  

During 1940-1941, "primary attention was given to the drug products that might be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended or suggested in their labeling."  

During 1940 there were a great variety of proprietary foods that were sold for use in the diet of infants and adults suffering from some ailment. "Many of them unwarrantedly were sold under extravagant claims and fancy names at exorbitant prices. ... the products of 199 manufacturers of special dietetic products were given attention during the year."  

In 1941, the enforcement activities of the Administration were primarily concerned with sulphathiazole tablets contaminated with phenobarbital, increased activity

16 Ibid.  
17 Walter G. Campbell, "Drugs and Drug Traffic," 1941 Britannica Book of the Year, p. 225.  
18 Ibid.
against filthy and unfit foods, and economic cheats resulting from war conditions that have shifted sources of production.19

The routine work of the inspector is the "backbone" of the Food and Drug Administration. A word of explanation as to just how the inspector functions on his day to day assignments may not be amiss.

The inspector may simply ask that the shipment be held until thorough investigation has been made. Full co-operation is usually offered. If not, an embargo is placed on the foods by state or local authorities. Field officers and Washington authorities are notified of these steps, pending laboratory study. Chemists and technicians analyze the consignment. Occasionally a mouse hair or a fly's leg or other undesirable material is found. Washington officials review all the evidence and in the event that the sample is pronounced filthy, the information goes to the solicitor's office, who in turn notifies the appropriate U. S. Marshal in the area involved. He is an agent of the Department of Justice, and it is his duty to seize the foods in the name of the United States. A proceeding called "Action Against the Goods" follows. The case may be tried in court before a jury; and if the decision stands, the goods may be destroyed.20

In the event of an economic violation, where for instance short weight is the charge, repackaging under supervision, with the cost borne by the offender, is the usual procedure that is followed.21

An inspector is equipped to make simple chemical tests


21 Ibid.
at the place where he finds what he considers questionable goods. He is invariably able to detect mineral oil in butter.\textsuperscript{22}

In one suspected plant in 1941 the mineral oil test was made on butter valued at $50,000. A good portion of it had to go to soap manufacturers.\textsuperscript{23}

The work of the food chemist is a valuable adjunct to that of the inspector. They are especially adept at studying mold count that the microscope finds in any product having a tomato base.\textsuperscript{24}

Tomato products continue as the most important field for the mold counter's activities. The micro analytic division of the Administration, however, uses this method for tests of jams, jellies, fruit butters, strained vegetables, butter and other foods, with such variations of technique as differences of tissue structure and other factors may require. ...\textsuperscript{25}

Food problems vary for the inspectors. The administration struck at the commercial fishermen of New England so hard in 1939, that by 1940 seizure of spoiled fish had been reduced from over a half-million pounds to less than 87,000 pounds. The fishermen have practically sterilized their holds.\textsuperscript{26}


\textsuperscript{23} \textit{Ibid.}, p. 53.

\textsuperscript{24} \textit{Ibid.}

\textsuperscript{25} \textit{Ibid.}

\textsuperscript{26} \textit{Ibid.}, p. 54.
Water apparently can be used in many guises and presents a few problems.

No consumer cheat is so profitable potentially as adulteration with water, and surprisingly it is one of the most difficult to detect and deal with under the law. Nothing can be said in defense of a manufacturer who sells water to consumers at food prices. The technical difficulty lies in the fact that water is a natural ingredient of practically all foods, and a normal amount of water is not an adulteration. The establishment in a court of law that a food contains excessive water and is therefore adulterated is a formidable legal problem. There is a crying need for legislative authority to set up legal standards for foods under which definite limits for water can be established. During the past year (1941), seizures were directed against such varied products as butter, jams and preserves, orange beverages, frozen eggs, tomato juice and fresh oysters in which the substitution of water was an important element of the violation.27

After we entered the war, enforcement activities continued in their usual routine fashion, although the work of the Administration increased in scope.

"... The first seizure and the first prosecution case under the new drug provisions were instituted in 1942. The seizure libel charged that the article was a new drug for which no application was effective. The prosecution case involved the falsification of an application."28

As the war wore on, greater supervision became necessary. "During the shortage of physicians for civilians,

27 Ibid.

public safety required intensified surveillance over the directions, warnings and therapeutic claims on the labels of preparations with which persons might attempt self-medication."29

While the war continued, drug problems increased.

"Drug shipments in violation of the Food, Drug, and Cosmetic Act increased in number because of substitutions, excesses and shortages in active ingredients and failure to meet standards of purity, packaging and labelling."30

"Seizures and prosecutions for shipments of alleged 'remedies' labelled with false and misleading curative claims were the highest in number after the enactment of the 1938 law."31

Seizures of drugs and devices in the United States in violation of the Food, Drug, and Cosmetic Act in the fiscal year 1945 increased by nearly 80% over similar actions in 1944. The largest increase involved proprietary preparations bearing false and misleading therapeutic claims or falling below labelled composition. ... Many of the misbranded preparations, attempting to exploit war-weary and nervously exhausted persons, bore unwarranted claims for restoring vigour, preventing sluggishness, or providing nutritional elements that should be present in the normal diet.32


31 Ibid.

The Food, Drug, and Cosmetic Administration is keenly aware of its responsibility to the public. The inspectors also make an effort to be thorough.

Some of the factors which are invariably given attention in sanitary inspections are:

1. Human behavior.

2. Rats, mice, and other vermin.

3. Flies, roaches, water bugs, and other insects.

4. Equipment and utensils, and the provisions for cleaning these articles.


6. Toilets, washing facilities, and their accessibility.

7. The plant.

8. Waste disposal, including methods of sewage disposal of the plant.

9. Conditions of storage and handling of products.

Nearly all FDA inspectors are chemists as well as detectives. While walking through a vinegar plant an inspector found several barrels of acetic acid hidden under a canvas cover. The inspector charged the company with using acid to adulterate pure cider vinegar. The vinegar manufacturer had a good alibi in court for the presence of the

acid and offered a scientific analysis of his product as part of his defense. The Food and Drug Inspector was able to convince a jury that by the defense witnesses having admitted the presence of minute traces of sulphur in the finished vinegar positively demonstrated that the sulphur was a carry-over from the dried apples which had been improperly combined with the acetic acid. 34

Another time abnormal imports of teeseed oil was noticed. With pure olive oil bringing high wartime prices, adulteration of it with the teeseed oil was suspected. After trailing trucks, checking deliveries, and continuously watching certain warehouses, enough evidence was gathered to bring charges against a distributor of olive oil. The FDA was challenged to prove its contentions in court. The FDA proved that by adding certain chemicals to pure olive oil a pink mixture would result if teeseed oil was present. The olive oil distributor was convicted. 35

Following the death of a woman user in 1942, the American Medical Association and the Food and Drug Administration working together drove faulty "heatless permanent waves" where sulfide solutions were used off the market. Present heatless wave solutions are regarded now as safe by the


During 1945 in the Middle-West an inspector was making a routine check of a butter-making plant. In looking into the shipping room he found thirty-five mice. Upon asking about the mice, the manager indicated he did not like cats, so he disposed of the cats, thus giving the mice free rein. Continues the report on this case:

The inspector went to work, and what he found is not pretty to talk about. His microscope revealed maggots and rat hairs in the butter. The fluorescent lamp showed traces of rat urine on the cloth used to cover the tubs. The inspector pulled a large mouse by the tail out of a can of milk. That night the plant was closed down, and shortly thereafter the owner paid a sufficiently heavy fine to remind him to be more careful in his choice of managers in the future.

An inspector in the Eastern district, upon walking into a bakery where they were making pretty pink cooky filling, found "hundreds of thousands" of cockroaches. The superintendent promised to clean up the room. When the inspector went back the pink-cooky room was immaculate. But he walked over to the warehouse where the flour was kept, and found unmistakable evidence of rats. When this was called to the attention of the manager, metal flashing was placed around the floor and eight inches up the wall to keep...

36 Ibid., p. 557.
37 Rita Halle Kleeman, "Food and Drug Cop," Collier's, CXVI, 23, (Sept. 1, 1945).
38 Ibid.
the rats back. On a third visit, in another part of the plant, the inspector found 120,000 pounds of decomposed eggs and a number of gallons of insect-infected chocolate liquor. 39

The friendly manager of the plant made one serious mistake, and that was when he reminded the inspector there was a war on and the firm had to finish this large (insect-infected) order for the armed forces and he did not like interference with production.

This was one time the inspector exercised his authority in a hurry. A re-check of the same plant found a new manager, new foremen, a completely renovated building, and an inspector employed by the firm to see to it that all regulations were complied with properly. 40

"Abortifacient pastes" for the producing of abortions, which came out of Germany in the '30s, have ever since been a serious problem in the enforcement activities of the Administration. In one instance, where several injuries and four deaths were traced to the activities of one manufacturer, the inspectors discovered that he was warning his customers that his product might go off the market and urged them to stock up. As soon as he was imprisoned a former employee was

39 Ibid.
40 Ibid.
bringing out the same product under another name.\footnote{Kleeman, \textit{op. cit.}, p. 23.}

During 1945 inspectors uncovered various frauds perpetrated upon the public. Such things as barnyard peat from Wisconsin selling as a "cancer cure" for $1.25 a pound. "Sunlit" ocean water at $5 a quart, a diabetics "cure" guaranteed to give "lasting relief"; a "Breasts of Youth" developer made of cold cream and alfalfa, selling for two dollars a jar were among other frauds. Another was a "miraculous" cure discovered by a shepherd in an isolated region of the Northwest, and made of what would most easily be "discovered" by a shepherd.\footnote{\textit{Ibid.}, p. 29.}

The year's prize device was an "electric" belt, the Magnetiray, guaranteed to cure asthma, arthritis, Bright's disease, diabetes, plus other ailments. The inventor, a Texas doctor, wired it with an induction coil and a flashlight bulb so it would go on and off most impressively. He sold hundreds of them in the South, Middle West and Pacific Coast areas at $75 apiece. It took two years searching to catch up to the doctor and convict him.\footnote{\textit{Ibid.}}

The Food and Drug Administration is willing to back down if it finds it has made a mistake. In 1944 a shipment of vitamin capsules was seized, in Minneapolis, for

\footnotesize{41 Kleeman, \textit{op. cit.}, p. 23.}

\footnotesize{42 \textit{Ibid.}, p. 29.}

\footnotesize{43 \textit{Ibid.}.}
being deficient in riboflavin. When the manufacturer requested the Administration to retest its product and in so doing found it was wrong, FDA in turn asked the district attorney to dismiss the case. 44

Conditions such as this one sometimes confront the Administration in its enforcement capacity. Trying to convince a jury is at times a long and unsuccessful process. In a trial involving the seizure of a nostrum represented as a cure for sixty-nine distinct diseases, which lasted sixteen weeks, a jury failed to agree on a verdict. 45

One could go on endlessly reciting violations uncovered by the able inspectors of the Administration. However, one more example.

During the war a serious problem arose on the civilian front of the use of barbiturates. Used under a physician's direction, it ranks as one of the great discoveries of modern science. But in Waco it was misused. 46

To prevent such abuses, the Food and Drug Administration has listed barbiturates as a drug that must be sold at retail only if the customer has a doctor's prescription. 47


45 Ibid.

46 Wallace Werble, "Waco was a Barbiturate Hot Spot," Hygeia, XXIII, 432, (June 1945).

47 Ibid.
In Waco, Texas, there were sixty known habitual users of barbiturates. A hard working young wife, supporting a shiftless husband and twin sons, tipped off Inspector Moses of the FDA to the source of supply, Fadal's Drug Store. This came about when the father gave these "goof" balls to his 5-year old child, the mother could put up with it no longer. Inspector Moses soon discovered that the only place he could buy barbiturates in Waco without a prescription was at Fadal's. The store's invoices and prescription records revealed that, during the previous eighteen months, 45,604 tablets had been sold without prescriptions, and only 289 tablets on prescription.48

Fadal, in 1945, pleaded guilty, was fined $600, was given a suspended six month jail sentence, and placed on probation for several years.49

Barbiturates, so far have not been placed under the jurisdiction of the Federal Narcotic Bureau, and the FDA staff is not set up to keep constant watch over more than 60,000 possible outlets for this drug. So the FDA does what it can where there are flagrant violations.50

Walter G. Campbell retired in 1944 as Administrator of

48 Ibid., pp. 432-433.
49 Ibid., p. 433.
50 Ibid.
the Food, Drug, and Cosmetic Administration. He had given close to forty years of government service. Wallace Werble, a correspondent for many years in Washington, was not stingy in his praise. Werble wrote two consecutive articles in *Hygeia* complimentary to Campbell's great public service.51

**Court Decisions.**

In presenting any material under the heading of court decisions, it must be borne in mind that there are scores of federal decisions on various phases of the Act. The government publishes quarterly the "Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act." In any such "Notice" you will find individual cases listed in the following manner: by number, indictment returned, alleged shipment, label in part, violation charged, disposition of case; or, number of case, libel filed, alleged shipment, product, violation charged, disposition of case; or, number of case, information filed, alleged shipment, label in part, violation charged, disposition of case.

The criminal cases most frequently end with a plea of guilty or nolo contendere, a payment of a fine, and confiscation of the goods seized.

Those cases, civil or criminal, that have as a point at


issue the interpretation of a regulation or standard, or a challenge of the applicability of a section of the law itself, are the kind of cases that mostly affect what the consumer is going to receive for his purchase.

The cases listed in this report are a mere sampling of the cases that travel through the courts. Yet they illustrate the varied, and sometimes complex, problems that confront the enforcement agency, the courts, and indirectly the public.

Judge Patrick T. Stone of the United States District Court of Wisconsin, in United States v. 62 Packages, More or Less, of Marmola Prescription Tablets, stated in his decision in 1943:

The Federal Food, Drug, and Cosmetic Act was not made for experts, nor is it intended to prevent self-medication. The purpose of the law is to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze. It was enacted to make self-medication safer and more effective, and to require that drugs moving in interstate commerce be properly labeled, so that their use as prescribed may not be dangerous to the health of the user. It should receive a liberal construction.52

It perhaps is well to bear in mind the responsibility of the manufacturer under the jurisdiction of this Act. It has been pointed out by the Supreme Court under both the 1906 and

1938 Law, with particular reference to Sections 201(n) and 502(f) which govern labeling.

In U. S. v. 95 Barrels, More or Less, Alleged Apple Cider Vinegar, (1924) the Supreme Court stated:

The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs, and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act.53

Almost twenty years later, 1945, in U. S. v. Dotterwech, the Supreme Court said:

The purpose of this legislation thus touches phases of the lives and health of people which, in the circumstances of modern industrialism are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.54

In a contested action involving adulteration of tomato paste with insect fragments, tried before the court without a jury, the court in finding for the Government stated, among other things:55

53 Ibid., p. 270.
54 Ibid.
There can be no doubt that this section (402(a)(4)) of the act was designed to protect the aesthetic tastes and sensibilities of the consuming public and that the visible presence of such material in food would offend both. Conceding this, the claimant argues that the statute is directed only to filth which is perceptible by the consumer. With this I cannot agree. To so interpret this section of the statute would largely deprive the public of the protection it seeks to give. The consumer ordinarily requires no governmental aid to protect him from the use of food products the filthy adulteration of which he can see, taste or smell. What he really needs is government protection from the food products the filthy contamination of which is concealed within the product. I am quite clear that it is the intent of the statute to bar such products from the channels of interstate commerce.56

In a criminal trial in which some of the sessions were held in the laboratories of both the defendant and the Food and Drug Administration, involved the interstate shipment of a product labeled as "Pituitary Extract Obstetrical (10 International Units per cc)" , alleged to be both adulterated and misbranded in that it possessed a potency twice that declared on the label,57 The court found the defendant guilty.58

Court interpretations of new provisions contained in the 1938 law are growing in volume and in scope. Several important decisions of issues arising from actions involving these

56 Ibid.
57 Ibid., pp. 19-20.
58 Ibid., p. 20.
provisions were handed down by the Federal courts in 1945.59

It is the general rule that statutes imposing forfeitures, being penal in nature, are to be strictly construed in favor of the defendant. ... But in United States v. Stowell, 133 U. S. 1, it was held that statutes enacted to suppress a public wrong although they impose penalties of forfeiture, are not to be construed strictly in favor of the defendant but should be fairly and reasonably construed so as to carry out the intention of Congress. The Federal Food, Drug, and Cosmetic Act was enacted in the interests of the public welfare to protect the public health, and the courts must give it effect according to its terms.60

The following case illustrates an unsuccessful attempt to evade the law by statements made on the label.

A seizure had been made of a consignment of tomato catsup containing benzoate of soda which was labeled in part "Tomato Catsup with Preservatives - Does not comply with government standard." The standard of tomato catsup does not authorize the use of benzoate of soda as an ingredient. The district judge held the product to be in violation of section 403(g) of the Food, Drug, and Cosmetic Act, and this decision was affirmed by the circuit court. In its opinion the circuit court stated, in part:

The condemned food is tomato catsup, and purports to be tomato catsup. If producers of food products may, by adding to the common name of any such product mere words of qualification or description, escape the regulation of the Administrator, then the fixing of a standard for commonly known foods becomes utterly futile as an instrument for the protection of the consuming public.61

Another important case establishing a definition of proper


60 Ibid., p. 53.

61 Ibid., p. 55.
ingredients is considered an outstanding one by the FDA.

The first case to reach the Supreme Court of the United States testing the propriety of excluding an ingredient was Federal Security Administrator v. Quaker Oats Co. That case involved the exclusion of vitamin D from farina. The Administrator had established two standards of identity, one for farina and one for enriched farina. The standard for farina excluded all vitamin and mineral additions. The standard for enriched farina required the addition of vitamin B₁, riboflavin, niacin acid and iron; vitamin D was one of the optional ingredients that could be added. There was evidence of widespread deficiencies of vitamin B₁, riboflavin, niacin acid, and iron and a showing that where a diet was deficient in one of these it would probably also be deficient in the others. The Administrator found that diets of infants and children were deficient in vitamin D. He then prescribed the standards for two foods, one without nutritional enrichment and the other a nutritionally improved product. The product of the Quaker Oats Company "Farina with Vitamin D" conformed to neither standard. The Quaker Oats Company strongly contended that the statute did not contemplate the exclusion of a "wholesome and beneficial ingredient" from a food by a standard. It further urged that since its product was properly labeled "Farina with Vitamin D" there could be no confusion among consumers.

The Supreme Court rejected these contentions. It stated: Both the text and legislative history of the present statute plainly show that its purpose was not confined to a requirement of truthful and informative labeling. False and misleading labeling had been prohibited by the Pure Food and Drug Act of 1906. But it was found that such a prohibition was inadequate to protect the consumer from "economic adulteration". The remedy chosen was not a requirement of informative labeling. Rather it was the purpose to authorize the Administrator to promulgate definitions and standards of identity "under which the integrity of food products

can be effectively maintained." 63

The Court also said: "The statutory purpose to fix a definition of identity of an article of food sold under its common or usual name would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition." 64

The Quaker Oats decision strengthened the regulatory powers of the Administrator. 65

In New York State a question of injunctive relief arose under the Federal Food, Drug, and Cosmetic Act. In this case:

The government sought an injunction against the defendants for the purpose of preventing them from shipping into interstate commerce, milk products which were allegedly prepared or held under insanitary conditions whereby they might have been contaminated with filth. The contention of the defendants that an injunction ought not to be granted was overruled by the Court on the ground that under the Federal Food, Drug, and Cosmetic Act, the right to injunctive relief is specifically authorized, and the government is not required to prove irreparable injury or other matters usually prerequisite for such relief. There was some question raised as to the meaning of the term "filthy" in the Act. The Court declared that the word was to be construed in its usual and ordinary sense. United States v. Adlers Creamery, Inc., Samuel Adler, Inc., and Samuel Adler. United States District Court, Southern District of New York, February 8, 1946. 66

That the powers of the FDA are not unlimited is shown in the following case:

63 Ibid., pp. 23-24.
64 Ibid., p. 24.
65 Ibid.
Defendant purchased a device, called a Spectro-Chrome, for the use of himself and his mother for the curing of various ills and ailments. The manufacturers of the machine represented, through a prospectus, that the machine through the use of various color combinations, could cure or alleviate divers physical ailments. In a previous proceeding against the manufacturers of the machine, the government had obtained a judgment that it was a fraud. In the instant proceeding, the government claimed the right to take the machine from the home of the private individual, although he had bought and paid for it, on the theory that because the machine had been shipped in interstate commerce, the government had a right to seize and condemn it under the authority of the Food, Drug, and Cosmetic Act. The Court denied that right.

It said ... On what conceivable basis, under our Constitutional guarantees, can the government deny to an adult individual the right to believe in and seek to cure himself of physical ailments by any means he chooses, so long as the means chosen is not inherently dangerous or harmful? I know many people who wear charms, including some who carry the lowly potato to keep disease away, and I had always thought they had a right to do this. Incidentally, I have no doubt that many get help in this manner. ... United States v. One Article of Device labeled "Spectro-Chrome" and accompanying labeling. William Ray Olson, Claimant. United States District Court of Oregon, April 4, 1946.

More cases, however, are decided in favor of the FDA. Said one federal judge:

The Food and Drug Act was passed as a protection to the uninformed, that they might be assured that an article purchased was what it purported to be. ... Certainly the average consumer would not be put on guard that a compound called "Elixir Terpin Hydrate and Codein (Special)" was not the elixir of terpin hydrate and codein listed in the Formulary. The word "special" might well signify to him merely that the ingredients were especially pure or that the product was manufactured with

67 Ibid., p. 276.
special care. If a manufacturer wishes to use a National Formulary name for a nonconforming product, it is his duty to give the public unmistakable notice that in its composition there has been a departure from the formula given in the Formu-

lary. United States v. Five One Pint Bottles, etc., of Elixir Terpin Hydrate and Codein (1934), 9 Fed. Supp. 990.68

Another federal judge, upholding the validity of microscopic evidence declared:

Nor am I impressed with the testimony that the variable sense of smell and taste is more dependable in detecting rot than the microscopic procedure adopted by the Government. Certainly the question of adulteration would rest upon tenuous ground if reliance or conclusion as to the character of the product shipped were bottomed upon conflicting evidence as to the smell or taste of the article sought to be condemned. United States v. 935 Cases, etc., of Tomato Puree (1946), 65 Fed. Supp. 503.69

Sometimes a manufacturer tries to impress the consumer beyond the claims on the label.

Many manufacturers are careful to keep the claims of the package within the limitations of the act, but make unwarranted claims in circulars and other promotional material. ... In several decisions beginning in 1942, the courts have defined the word "accompanying" in terms broad enough to encompass such shipments when the articles and literature are brought together at destination. ... (In 1946) the District Court of the Southern District of California stated: I hold that the word "accompany" as used in the act means that when a drug

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and a related circular, having a common destination, come together at their destination, they are united and become one insofar as the buying public is concerned, each, in effect, accompanying the other, whether they arrived at their common destination simultaneously or otherwise. 70

Thus are presented samplings of a few of the problems that reach the courts for determination.

CHAPTER VI.

WARTIME ACTIVITIES

The wartime activities of the Food and Drug Administration have not, as yet, been extensively reported. Yet, we already are aware that the Administration was very much "on the job" during the war, and in the immediate post-war period. Concerning its wartime responsibilities the Administration reported:

To preserve the integrity of the food and drug supply of a nation at war is now the primary responsibility of the Food and Drug Administration. ... While there are many problems peculiar to military and civilian supplies, their common basic requirement is purity and quality, which must be maintained despite the stresses of wartime production and distribution. A second responsibility is to make available to other war agencies the knowledge and skills of its staff of scientists trained in many specialized fields, to assist in solving wartime problems.¹

Information accumulated during years of enforcement operations includes pertinent data on most of the more than 50,000 food and drug factories and processing establishments that ship products in interstate commerce; and encompasses the results of a vast amount of technical study relating to methods of detecting adulterations, to the normal composition of various items, to the vitamin potency of foods and drugs, to the toxicities of a wide variety of substances, and to the therapeutic efficacy of innumerable preparations.²

A general statement as to the effect of war in relationship to the Food and Drug Administration is given by the

¹ "War Activities," Annual Reports, Food and Drug Administration, 1941-1942, 1942-1943, p. 1.
² Ibid., p. 2.
Chief of the Eastern District.

Wartime speed-ups, restrictions, dislocations, and stresses and strains, are influences which promote food and drug adulterations. The attendant abnormal circumstances of war conditions multiply the frequency of these occurrences, extend their scope, and aggravate their seriousness from the standpoint of effect on public welfare. Wartime brings increased production for our armed forces, our allies and our civilian population. This is accompanied by manpower shortage and by difficulty in securing suitable replacements and repairs for machinery and equipment employed in the production and processing of foods and drugs. War is necessarily a period when new sources of supply must be found, when new products must be developed, when storage and transportation facilities normally sufficient for the country's needs are greatly over-taxed. These abnormalities together with essential government restrictions on commerce and trade, and the tendency of malefactors to take advantage of emergency conditions, all have their sequelae and concomitant effects in causing the adulteration of foods and drugs through carelessness, by accident, by reason of deterioration of products handled out of normal routine and by malicious design. Any one of these causes may result in food and drug adulterations or a combination of them may produce this effect.3

Research.

The Government purchases its supplies on specifications. The Food and Drug Administration had the job of testing all medical consignments received by the Army, including those sent to our allies. These tests included chemical analyses, bacteriological examinations, and bioassays.4

One of the most important health problems that faced


the armed forces in the early stages of the war was being able to have insect repellents at hand. Two things FDA had to certify to were how toxic, and how irritating were the repellents. Those that passed the FDA tests were recommended for use.5

Substitutes for quinine, such as atabrine, the toxicity of a sunscreen, and the sterility in sulfa drug powders for use in open wounds, were among the numerous problems that were solved for the armed forces by the laboratory men.6

Members of the staff furnished technical advice to the War Production Board, Office of Economic Warfare, Office of Price Administration, War Food Administration, War and Navy Departments, and the National Research Council. Staff members also served on such boards and committees as the Food and Nutrition Board, Vitamin Committee of the Combined Food Board, and the Provisions Committee of the Federal Specifications Executive Committee.7

The statements in the annual report covering the period from July 1, 1943 to June 30, 1944 reflect the seriousness of what was going on throughout the world at that time. The research facilities, as well as the enforcement staff, were

5 Ibid., p. 4.
6 Ibid., pp. 4-5.
7 Ibid., p. 6.
taxed to the utmost in carrying out assigned work. On June 30, 1944, the Administration only had 852 employees, of whom 352 had been added to the force since Pearl Harbor.8

There was not a duplication of effort and a waste of time in carrying on research programs at the request of various war agencies in World War II as there was during World War I.9

A most important function the Administration rendered the Army and Navy throughout the war was the control of penicillin for them.10

On the civilian front the inspectors were trying to protect the populace against substitutions and departures from the normal in food, drug, and cosmetic supplies.11

The most serious handicaps in solving these civilian front problems were the lack of transportation and storage, particularly adequate cold storage, the exposure of foods and drugs to rodent and insect contamination due to lack of proper warehouses.12

There is a measure of comfort in the following statement:

8 "War Activities," Annual Report, Food and Drug Administra-
tion, 1944, p. 1.

9 Ibid., p. 2.

10 Ibid., pp. 2-3.

11 Ibid., pp. 4-5.

12 Ibid., p. 5.
Deliberate attempts of the minority fringe to exploit emergency conditions in order to make fraudulent profits from war supplies and civilian commodities, while numerous, were confined to a comparatively small number of operators. Forward-looking men in the industries recognized that both the public and the manufacturers' interests demand pure and honestly labeled products in war as well as in peace. The success of joint efforts to suppress such frauds is reflected by the fact that ersatz products encountered on the market after a 4-year war are still regarded as news items rather than as an inevitable result of warborn conditions.13

With the outbreak of hostilities in Europe, causing an immediate slump in our regular imports, the change to South, Central American, and Mexican ports for most of our imports created problems because of those countries unfamiliarity with the requirements of the Food, Drug, and Cosmetic Act. As the war wore on these countries' exporters learned to comply with the Act in order to land their commodities here.14

Problems to solve did not cease when the war stopped:

With hostilities ended, the surplus foods and drugs purchased by the Government interpose a serious regulatory problem. Many drugs that originally met all tests of purity and safety for use are fortunately no longer needed by the armed services. ... Large quantities of food items also have been subjected to the fortunes of a global war. Many other articles have never left the country, but each lot at least has a storage history demanding

14 Ibid., p. 2.
inquiry before safe distribution can be attempted.\textsuperscript{15}

In the cargoes of returning American vessels, "the first items requiring attention were foods condemned as unfit for human consumption." These were discharged at the most convenient port and the problem of disposal became serious.\textsuperscript{16}

A plan of control was worked out with the naval and maritime authorities whereby discharged ships' stores are segregated at the ports and held for Food and Drug Administration inspection exactly as if they were imported foods. Only portions found in satisfactory condition are permitted entry and the remainder is destroyed or denatured for appropriate nonfood use.\textsuperscript{17}

Research on repellents continued. "While a number of repellents superior to any prewar preparation were adopted, search was still under way for a completely satisfactory repellent when the war ended. ... DDT is probably the most effective lousicide and insecticide to be developed."\textsuperscript{18}

It was the FDA, at the request of the Army and the Office of Scientific Research, that conducted experiments on articles developed for protection against the effects of war gases. Had the need for their use arisen, we would have had some measure of protection.\textsuperscript{19}

When the National Research Council developed a series

\textsuperscript{15} Ibid., p. 4.
\textsuperscript{16} Ibid.
\textsuperscript{17} Ibid.
\textsuperscript{18} Ibid., p. 6.
\textsuperscript{19} Ibid., p. 8.
of basic rations for combat troops, the FDA undertook studies to determine their vitamin content, and how these concentrated foods would stand up under varying storage temperatures and conditions.20

The Food and Drug Administration, working hand in hand with the War Production Board, contributed its research knowledge in the developing of satisfactory synthetic rubber materials for various uses, the preventing of the use of indium and cadmium as substitutes for aluminum in food and cooking utensils, the safe use of butylene glycol as a humectant for tobacco, and permitted use of dehydro-quinidine as a substitute for the cardiaactive drug quinidine.21

Field Men.

So far in this chapter, what has been presented has had to do in the main with research activities of the Food and Drug Administration. Now will be presented some material relating to what the field men came across and had to contend with over the same period of time.

When pure oil became unobtainable from Italy, Greece, Tunisia, Turkey and Spain many suppliers bought up the wholesale and retail stocks in South America and the West Indies. Most of the lots were found to be adulterated with cottonseed oil or other less expensive edible oils though labeled

20 Ibid.
21 Ibid., p. 9.
generally as: "Pure Virgin Olive Oil."22

Products that were entirely spurious because the natural sources of supply were shut off during the war were marjoram, sage, thyme, savory, and laurel leaves; among the drugs were ipecac root, rhubarb, bella-donna root.23

One result of sugar rationing, importations of filthy-contaminated honey and candies containing non-permitted coal-tar dyes and tals.24

These illegal, and at times dangerous, substitutes appeared in the many and varied foods that go to make up the American diet; grated carrots for fruit content, asafetida as a garlic flavoring, mineral oil for vegetable oils, thirty per cent butter fat "Victory Spread", and "Soya Butter", which contained no butter fat, for regular butter; horse meat for beef, cocoa shells for cocoa, roasted cereal, chick peas, soybeans, and chicory for coffee; a cereal product for coconut shreds, puffed wheat and soybeans for peanuts in peanut brittle; rice flakes and cracker crumbs for ground nut products in cakes and confections; dried whey and soya flour for non-fat milk solids in bakery products;

23 Ibid., pp. 458-459.
24 Ibid., p. 459.
ground pecan shells flavored with oils for pure-spice; various syrups were grossly adulterated with water; and shelled pumpkin seeds were sold as salted nuts.  

Even a long established drug manufacturer succumbed to temptation and put out an anti-malarial containing no quinine under the regular trade name he had been using for years. The government seized 42,000 bottles of the substitute remedy.  

Materials used for containers during wartime have resulted in food and drug adulteration. Examples are bottles made from worn out molds resulting in slivers of glass being found in the contents. Substituting lead tubes thinly lined with tin and wax for packing silver-picrate, a venereal prophylactic. Chemical reaction with the lead rendered the product impotent and worthless for the purpose for which intended. Rubber is used extensively as closure for various forms of medicines, including those which are used parenterally. Some rubber substitutes caused serious injuries to patients when the medicine came in contact with the rubber closure. Tin shortages caused return to the use of cadmium for metal plating purposes. The result was cadmium food poisoning after consumption of

26 Ibid., pp. 460-461.
an acid punch material from such carriers.27

Insecticide shortages were responsible for much of the adulteration of fruits and leafy vegetables.28

Manufacturers anticipating shortages and higher prices in certain lines began stock piling to reap greater profits. The result frequently was condemnation by the FDA. One firm storing senna leaves had 191,700 pounds seized "because of extreme insect infestation which rendered it disgustingly filthy and unsuitable for use."29

A conserve manufacturer entered into a contract with the Navy to remove its garbage from a Naval training station. He in turn recovered the citrus peels to use in his conserves. "The recovered material was disgustingly filthy, having been associated with decomposing materials and filth of all kinds."30

In another instance filthy and decomposed chicken fat was recovered from hotel garbage. Excreta-smeared chicken feet were bought from butcher shops. Soup resulted from this combination.31

27 Ibid., pp. 461-462.
28 Ibid., p. 462.
29 Ibid.
30 Ibid., p. 463.
31 Ibid.
Due to labor shortages and inexperienced help, some serious adulterations occurred, particularly in the drug line. Examples: "calcium chloride U. S. P." was found to be calcium chloride, a deadly poison; "Codeine Sulfate Tablets" turned out to be morphine sulfate; Phenobarbital tablets were mistakenly labeled 7½ grain sulfathiazole tablets. Phenobarbital is a strong hypnotic. Larkspur Lotion was mistakenly labeled "aromatic spirits of ammonia." Hyper-sedative potassium iodide was substituted for potassium bromide constituent. In each instance innocent people suffered.32

According to the Chief of the Eastern District of the FDA, refugees created a number of serious problems for the enforcement officers. These people are familiar with European standards, and sometimes show little regard for ours.33

Their illegal and fraudulent operations included such examples as the following: the sale of deceptive soldier's gift packages to send overseas. After the packages were paid for ($5.95) the firm failed to deliver them. Another firm selling gift packages had to know a great amount of information regarding the recipient. They were turned over

32 Ibid., pp. 464-465.
33 Ibid., p. 465.
to the F. B. I. for further attention. These refugees also engage in the manufacture of a number of harmful food substitutes.34

War-born conditions were at least a contributing factor that brought about conditions described in the following quotation of civilian life.

Wartime stresses and strains create nervousness and possibly some relaxing of morals. These conditions have contributed to the increase of the sale of barbiturates, benzedrine, cantharides and the sulfa drugs over the counter without prescription; barbiturates for sedative purposes; benzedrine to ward off fatigue; cantharides for stimulation; sulfa drugs for self treatment of gonorrhea. All are dangerous to users. ... In one case alone in possession of one dealer, we were obliged to seize 1-3/4 million rubber prophylactics, on the charge that they were worthless because of imperfections. ...35

Among the unfair advantages taken of the public during rationing were these: packages labeled "100 Lbs. of Onions" actually weighed 60 pounds; saccharin, a sweetener having no food value, became an adulterant in manufactured foods; quickly cured hams were sold as "Ready to Eat," when in 1942 according to the U. S. Public Health Service, ham topped the list as a causative agent of food poisoning resulting from staphylococcus infection.36

There were food and drug manufacturers that

34 Ibid., pp. 465-466.
35 Ibid., pp. 466-467.
36 Ibid., pp. 468-469.
misrepresented and knowingly sold under false labels "Imported Swiss Cheese," "Vanilla Extract," "100% Grade A Pure Vermont Maple Syrup," and other products as well.37

Post-War Conditions.

These two official rules, promulgated after the war, apply to the disposition of government owned condemned articles:

Drugs: Drugs, chemicals, biologicals and other medical supplies which are unsafe for use, deteriorated, or bear an expired date of effectiveness will be destroyed.

Foods: Before any item or lot of subsistence supplies which have been determined by competent authority to be unfit for human consumption is disposed of by sale or otherwise, it will be brought into conformity with the requirements of the Federal Food, Drug, and Cosmetic Act by denaturing so as to render the product unusable for human consumption.38

Large quantities of dried navy beans that had deteriorated in storage and had been condemned and sold for animal feed were found in the channels of the food trade. The Army had condemned a large lot of dried eggs and labeled them "unfit for human food." These eggs were found later in bakeries. Army deteriorated pretzels, biscuits, crackers, dehydrated fruits, dried beans were offered for sale by various dealers in Virginia, for food purposes.39

37 Ibid., pp. 469-470.
38 Ibid., p. 473.
39 Ibid., p. 474.
By agreement, the Army did not have to have complete labels on certain dangerous drugs that were administered without medical supervision under battle conditions. However, it was agreed that any such drugs that were usable and offered for sale following the war would have to be relabeled to meet the requirements of the Food, Drug, and Cosmetic Act before sold.  

The several government agencies that had the authority to distribute war surplus goods jointly agreed on a policy of safety to consumers at the instigation of FDA. They further agreed that the best course was to institute a system of inspection at the source of disposal. Actual inspections by agents of the Administration of surplus articles and determination of their suitability or unsuitability were made by physical examination.

These operations, too, have imposed a tremendous work load upon the limited force of the Food and Drug Administration, but they have had the effect of furnishing a large degree of protection to the consuming public.

By perusing advertisements in newspapers and magazines FDA found illegal drugs being offered for sale that came

40 Ibid., pp. 475-476.
41 Ibid., pp. 476-477.
42 Ibid., p. 476.
from Army "First Aid Kits" and "First Aid Packets." 43

The Army sold 700,000 empty tin cans labeled "Supper" ...
and "Breakfast" ... to a dog food manufacturer, specifically with the understanding that the buyer would obliterate the above labels. This the dog food manufacturer failed to do. He filled the cans with dog food, placing a paper label reading "Dog Food" over the Army labels. Many buyers, after seeing both labels on the cans, assumed that the contents were regular Army rations and fit for human consumption. 44

The same thing took place after the purchase of Army empty cans with lithographed labels of "Ham and Eggs" ... , "Meat and Noodles" by dog food manufacturers. In these instances the Food, Drug, and Cosmetic Act was violated and misuse of the U. S. Meat Inspection Legend as well. 45

During the war foreign exporters had no experience with, or knowledge of, the present Food, Drug, and Cosmetic Act; in addition many ordinarily exported food and drug products had been in storage during the entire course of the war. 46

Concerning the magnitude of this problem, the Administration reported:

43 Ibid., p. 478.
44 Ibid., p. 480.
46 Ibid., pp. 481-482.
By the end of the first six months after the war, a perfect deluge of misbranded, deteriorated, spoiled, and unfit products were knocking at the doors of the American ports of entry. Since that time the number of violative import shipments arriving has steadily increased from week to week. For many months it has been necessary to deny entry to an average of more than 100 cargoes each week.47

During the fiscal year ending June 30, 1946, 14,955,000 pounds of deteriorated insect-infested or filthy or moldy spices were refused entry into the United States at eastern ports alone, as violative of the Food, Drug, and Cosmetic Act. ... Much the same situation prevails in the case of crude drugs. Very large quantities have been offered from import in so highly deteriorated condition as to make them entirely worthless.48

Ships stores are landed in very large volume. ... Condemned stores having no salvage value are jettisoned or removed as garbage or galley waste and are dumped under Customs supervision. Condemned material having salvage value, such as fats, oils, grains, cereals and dried fruits, are entered through United States Customs and are denatured to render them unfit for human food, under the supervision of the Food and Drug Administration.49

In the postwar period we are experiencing critical shortages in certain basic food materials. Among these are edible fats and oils, cheese, sugar, and animal feeds.50

Policing of the food supply of the nation in the postwar era has revealed numerous instances of the use of mineral oil in whole or in part as a substitute for vegetable oil

47 Ibid., p. 482.
48 Ibid., pp. 482-485.
49 Ibid., p. 487.
50 Ibid., p. 488.
in mayonnaise, salad dressings, candy bars, toasted peanuts, potato chips, popcorn, lard, and other products. According to the Administration, "mineral oil is a worthless and dangerous food adulterant."\(^51\)

Frequent use of poisonous preservatives in food probably grow out of sugar shortages. The following poisonous substances have been found in foods: monochloracetic acid, quarternary ammonium solution, salicylic acid, borax, and thiourea.\(^52\)

After the war, many Navy and Coast Guard vessels found their way into fishing operations. In many cases the holds of these ships could not be satisfactorily refrigerated. Two million pounds of spoiled fish were kept out of the channels of the food trade as a result of the policing of the Food and Drug Administration.\(^53\)

Summing up the problems of the war and postwar periods, an FDA expert said:

> We have learned that war brings with it food and drug adulterations which seriously menace public health and are inimical to public welfare. We have learned that postwar conditions promote some of the same adulterations and bring many more in addition. It is obvious, therefore, that extreme vigilance is required of food and drug control officials to keep such practices in check if

\(^{51}\) Ibid.

\(^{52}\) Ibid., p. 490.

\(^{53}\) Ibid., p. 491.
public health and public welfare are to be conserved during such periods.\footnote{Ibid.}
CHAPTER VII.

OBSERVATIONS AND CONCLUSIONS.

On June 25, 1946, in New York City, the fortieth anniversary of the original Federal Food and Drug Act of 1906 was commemorated. The chairman said:

A meeting to commemorate the anniversary of this 1906 act is indicated, because it was a landmark in the social and economic progress of our country. For it was our first national food and drug law, in a basic sense; it had profound social and economic consequences, in protecting the public health and improving the food and drug order; and it led to the succeeding Federal Food, Drug, and Cosmetic Act of 1938, which is acclaimed as the strongest national law on its subject now in existence. ...

On this memorable occasion the Federal Security Administrator, referring to both laws, made this penetrating observation:

There is no way of measuring the results of our food, drug, and cosmetic legislation. It cannot be done with statistics. We cannot say how many lives have been saved because manufacturers are prohibited from selling injurious products. No one can roughly estimate what the public has been saved economically through prohibition of fraudulent labeling and deceptive packaging. What we do know is that this law, along with other social legislation, has served to contribute to our faith in our government. It has built up a respect for the integrity of our commercial institutions. It adds to our belief in the fairness and justice to be found in a representative form of government. It demonstrates the virility of our indefinable fusion of popular government and free enterprise.2


We should not forget that this law definitely has a dual purpose. It not only protects the health and pocketbook of the consumer, but acts as a valuable aid in protecting the honest businessman from dishonest competition. As one writer puts it:

... The honest businessman, like the consumer, has to be protected from the small fringe who engage in alteration, misbranding, and general corner-cutting in order to obtain competitive advantages over those who obey the rules of the game. Producers who use deceptive containers with false bottoms, pass off inferior and substandard ingredients, adulterate their products, and use false and misleading labels are very much in the minority. Yet their activities not only hurt us as consumers, but injure the businessman who seeks to abide by rules of fair dealing. Standards are necessary where a small group refuses to play the game squarely.5

From the information gained from the various sources it would appear that the present law gradually is winning over more advocates from among those over which the Act has jurisdiction. The writer just quoted continues:

The responsible producer recognizes his responsibility to the public. In fact, the Grocery Manufacturers of America recognized the importance of the Administration when they praised it for its "fundamental contributions to public health and scientific research." The Drug Trade News, in its issue of January 29, 1945, said: 'When truly understood, the obligations of the industries involved are precisely the same as those of FDA, a fact which justifies the closest and most intelligent cooperation between them.' The activities of the Administration are now being praised by many businessmen, despite the fact that they felt earlier.

in its history that it would adopt practices hostile to the best interests of their industries.\textsuperscript{4}

Confirming this point of view, we find such quotations as these from important industry officials:

Clarence Francis, chairman of the board, General Foods Corporation, says: The Food and Drug Administration protects the honest manufacturer as much as it protects the consumer. We support and approve it, just as we support the police force that keeps crooks from breaking into our homes. It has done a great work. We could not get along without it. ... It has not only done its work intelligently and sincerely, but industriously. It has also done its work honestly. To my knowledge, there has not been even a suspicion that its decisions have ever been based on anything except the honest judgment of the administrators. That is a great record.\textsuperscript{5}

H. J. Heinz, president of H. J. Heinz Company, says: The Food and Drug Administration is an outstanding example of how a government bureau, primarily created to police an industry, can contribute to the progress and development of such an industry through constructive criticism and sympathetic co-operation. ... It is held in highest regard by all reliable members of the industry. ...\textsuperscript{6}

The backbone of the Administration is its comprehensive research facilities and its absolutely impartial scientific approach in its findings. By this it has gained the respect of all segments of the public which are interested in pure food and drugs, as well as honest merchandising.

\textsuperscript{4} Watson, \textit{op. cit.}, p. 9.

\textsuperscript{5} Rita Halle Kleeman, "Food and Drug Cop," \textit{Collier's}, CXVI, 29, (Sept. 1, 1945).

\textsuperscript{6} \textit{Ibid.}
Many times under the 1906 Law the Administration officials felt that the courts were far too lenient with offenders. This attitude on the part of the courts has changed under the present law. A reading of almost any of the "Notices of Judgment" will demonstrate a greater willingness to impose the maximum penalties allowed under the law rather than the usual $1 and costs that were levied so frequently under the former law.

The law as it now stands has two definite limitations. The FDA has no control over toilet soaps, and no control over newspaper, magazine or radio advertising of food, drug, and cosmetic products. Obviously it will be beneficial to all concerned when toilet soap is under control of FDA. The same would hold true for advertising. Consumers would have a clearer understanding of what they are actually purchasing.

The distinction made between labeling and advertising during the Congressional "fight" that led to the passage of the Wheeler-Lea Amendment to the Federal Trade Commission Act, which specifically placed food, drug, and cosmetic advertising under the jurisdiction of the Federal Trade Commission has led to a fine line overlapping of authority, confusion among producers, and court decisions which give various definitions to labeling and advertising. The Federal Trade Commission, as well as the food, drug, and cosmetic interests opposed the Food and Drug Administration
As time goes by, all parties concerned are apparently finding the present arrangement one that is a nuisance and a time waster in enforcement activities of both agencies.

Shortly before Mr. Campbell retired as Commissioner he publicly urged a unification of federal government control over foods, drugs, and cosmetics, pointing out that:

To date the split in industry jurisdiction has not worked out. By one device or another FTC has edged itself into labeling control while Food and Drug has won court decisions permitting it to utilize advertising as a means of determining what a manufacturer means by his labeling.\(^7\)

The Federal Trade Commission apparently is ready to agree with the FDA, at least in part. Of recent date we find a four-point policy announcement in which the commission has pledged to co-operate with other federal agencies possessing regulatory power; to refrain from legal actions involving labeling or branding when it is the specific function of another agency; to recognize the labeling requirements of FDA in correcting false advertising; to take action against advertisers only when omission of facts jeopardize the health of the consumer. It is hoped that this policy will mean more consistency between the rulings of the two agencies.\(^8\)

\(^7\) "Crusader Quits," *Business Week*, 34, (May 6, 1944).

In spite of the fact that there is much published material about the Food and Drug Administration, very little of it reaches a wide audience. Food and Drug news rarely makes radio newscasts, or public information programs. The available material is in government documents, journals and magazines of relatively small circulation. As far as this writer was able to discover, only three newspapers, previously mentioned, in the entire United States ever consistently advocated, over a period of time, the advisability of having a strong pure food, drug, and cosmetic law.

Though the federal court calendars have frequent food, drug, and cosmetic violations coming up for hearings, the newspaper reporters, in making their rounds, apparently ignore most of these "crime stories." It may be that advertising space would shrink on the back pages if crime stories of this character were featured on front pages.

Yet it is difficult to resist the conclusion, as a layman, that the frequent reporting to the public through the press and radio of actual food, drug, and cosmetic violations would be of great assistance in raising the level of these commodities. Those producers that are consistently honest with the public would ultimately increase their sales volume because of the public's faith in their product.

Only four articles were found in two San Francisco papers over almost a year's period of time in looking for

In the San Francisco Chronicle of November 21, 1946, with a follow-up story on February 19, 1947, we find that "$8,000 worth of hog feed became $75,000 worth of food for human consumption" by the simple expedient of selling 600,000 pounds of Army condemned candy, cookies, and peanuts. The purchasers promised to cover the candy, cookies, and peanuts with fish oil to make it unfit for human consumption and didn't. The four individuals involved finally pleaded guilty to a charge they conspired to make false representations to the Government.\(^9\)

On November 30, 1946, the San Francisco Chronicle reported that the Italian-American Pasta Company was fined $2,000 after a plea of nolo contendere, "to charges it violated the pure food law in shipping filthy macaroni out of the state."\(^10\)

The San Francisco News, on December 16, 1946, reported that A. Schilling and Company "was charged with violating the Pure Food and Drugs Act by shipping contaminated spices to various Western cities. \(...\) The information also


charged the company with packing under insanitary condi-
tions."

The Food and Drug Administration at the turn of the
century was a small, well-meaning, but poorly co-ordinated
government bureau. When Walter G. Campbell became Chief
Inspector, forty years ago, he established a principle of
procedure of detecting violations as nearly at the source
as possible. As the bureau grew in scope and influence,
it has continued to use very effectively the basic prin-
ciple laid down by Campbell. \(^1\)

As a minimum requirement, the Federal Food, Drug, and
Cosmetic Act in its present form must be maintained. The
surest way of maintaining it is by "eternal vigilance" on
the part of a consuming public. In addition to the law
itself, spokesmen in the interest of the public should al-
ways see to it that the Food and Drug Administration has
funds, personnel, and equipment to do the job the law calls
upon it to do.

This law will be expanded and improved upon only when
a large enough segment of the public becomes interested
enough in its own health and welfare, and economy, to arouse
Congress to further beneficial legislation, and not until
then.

\(^{11}\) "Schilling Accused on Pure Food Laws," San Francisco
News, December 18, 1946, p. 22.

\(^{12}\) W. R. M. Wharton, "Its Inspection Evolution," Food-Drug-
By whatever means we make our living, there is one grouping that fits us all insofar as foods, drugs, cosmetics, or devices are concerned, and that is, all of us are consumers.

We naturally desire that, as time goes on, such legislation as this thesis encompasses should keep step with prevailing health, scientific, and economic conditions at a more accelerated rate than has been exhibited in the past. We would not like to see "pressure" politics in the future so powerful that it would take over thirty years hence to achieve fundamental changes in the law if they should be necessary for the good and welfare of the general public.

We take the optimistic point of view that the millions of people that make up our population do gradually become educated, enlightened, and responsive to the needs that create a high, thus healthful, standard of living for all. As a result certain groups will maintain a sense of awareness that will cause improvements or changes to take place in this Act, when and where needed. All of us should be grateful for such a piece of federal legislation as the present Federal Food, Drug, and Cosmetic Act.
A. BOOKS.


Kallet, Arthur, and F. J. Schlink, *100,000,000 Guinea Pigs*, Grossett and Dunlap, New York, 1940.


B. PERIODICAL ARTICLES.


"Challenge to FDA," Business Week, 64, (Sept. 27, 1941).


"Druggists vs. Grocers," Business Week, 57, (Nov. 16, 1940).

Eddy, Dr. Walter H., "It's Still up to Us," Good Housekeeping, CVII, 182 and 195, (Dec. 1938).


"FDA Loses," Business Week, 92-95, (Oct. 21, 1944).

"FDA Sustained," Business Week, 64, (Mar. 6, 1945).


"Flour Standards," Business Week, 57, (April 12, 1941).


"Food and Drug Bill Passed at Last," Business Week, 36-37, (June 18, 1938).

"Food Standards Committee of the Food and Drug Administration," Science, LXXXVIII, 234-235, (Sept. 9, 1938).


Guthrie, Jean, "Read the Label on the Can," Better Homes and Gardens, XX, 44-45 and 72, (June 1945).


"Is It A-B-O?" Business Week, 59-61, (April 19, 1941).


"New Prescription," Business Week, 70-72, (June 1, 1946).


"Reveal Formulas?" Business Week, 42-47, (Sept. 13, 1941).


"Same Tube, But --," Business Week, 42, (Nov. 9, 1940).


"Survey on A-B-C," Business Week, 26 and 31, (July 26, 1941).

"Symposium on Foods and Drugs," Canning Age, XX, 319-320, (July 1939).


"The Food Standards Committee of the Food and Drug Administration," Science, CI, 553-554, (June 1, 1945).


"War or No War," Business Week, 96, (Sept. 30, 1944).

"Warning Against Hormone Creams," Science Digest, XVIII, 49, (Sept. 1945).

C. PUBLICATIONS OF PROFESSIONAL ORGANIZATIONS.


"We Need a New and Strong Food and Drugs Act," American Journal of Public Health, XXXVII, 1286-1287, (Dec.


E. ENCYCLOPAEDIA ARTICLES.


F. Newspapers.


San Francisco News, December 18, 1946.
APPENDIX.

FOODS

STANDARDS

* The Act authorizes the Administrator to promote honesty and fair dealing in the interest of consumers by setting a reasonable definition and standard of identity and a reasonable standard of quality and fill of container for food.

HEALTH GUARDS

A food must not be injurious to health.

Candy must not contain alcohol or any "prizes" or other inedible substance.

* The Administrator may limit the amount of added dangerous substances that cannot be avoided in the manufacture of a food.

Food containers must be free from any substance which may cause the contents to be harmful.

Coal-tar colors contained in food must come from a batch certified as being harmless.

LABELING INFORMATION

The following facts must appear in the labeling:

1. The name and address of the manufacturer, packer or shipper.
2. An accurate statement of the quantity of contents.
3. If composed of two or more ingredients, and it is not a standardized food, the common or usual name of each ingredient must be listed.
* 4. The labeling of food for special dietary uses must bear information considered necessary to fully inform purchasers.
5. Artificial flavoring, artificial coloring or chemical preservative in foods must be listed in the labeling.
6. All the information required by the Act must be shown in the labeling in a form easily noticed and readily understood.

* In these instances the Federal Security Administrator is authorized to hold public hearings to receive evidence upon which the necessary regulations are based.
SANITATION

Food must be prepared, packed, and held under sanitary conditions.

A food must not be filthy, putrid, decomposed, or otherwise unfit.

A food must not be the product of a diseased animal.

PROHIBITED DECEPTIONS

Food labels must not be false or misleading in any particular.

Damage or inferiority in a food must not be concealed in any manner.

No substance may be added to a food to increase its bulk or weight or make it appear of greater value than it is.

A food must not be sold under the name of another food.

Imitations and food substandard in quality must be so labeled.

A substance which is recognized as being a valuable part of a food must not be omitted.

Food containers must not be so made, formed or filled as to be deceiving.

DRUGS

HEALTH GUARDS

Before a new drug is placed on the market an application must be filed with the Federal Security Administrator. This application must be accompanied by ample evidence of the safety of the drug.

Drugs must not be dangerous to health when used in accordance with the printed directions.

Containers for drugs must not be composed of any poisonous substance which may render the contents harmful.

Drug products must not contain any filthy or decomposed substance.
Drugs must not be prepared, packed, or held under insanitary conditions.

A drug liable to deterioration must be suitably packaged and informatively labeled.

Drugs that do not meet official standards must be labeled to show exactly wherein they vary from the standards.

Official drugs must be packaged and labeled as prescribed by the official pharmacopoeias and formulary.

No substance may be added or substituted to reduce the quality or strength of any drug.

A drug must not differ in strength, purity, or quality from that claimed in its labeling.

Coal-tar colors contained in drugs must come from a batch certified as being harmless.

LABELING INFORMATION

The labeling of a drug must bear the following information:

1. The name and address of the manufacturer, packer, or distributor.
3. A statement of the quantity or proportion of certain habit-forming drugs together with the statement "warning—may be habit forming."
4. (A) The common or usual name of the drug.
   (B) When the drug is composed of two or more ingredients, the common name of each active ingredient and the amounts of certain ingredients listed in the Act.
5. Adequate directions for use.
6. Warnings against unsafe use by children.
7. Warnings against use in disease conditions where cautions are necessary to insure against danger.
8. Warnings against use in an amount or for a length of time or by a method of administration which may make it dangerous to health.
9. All the information required by the Act must be shown in the labeling in a form easily noticed and readily understood.

PROHIBITED DECEPTIONS

Drug labeling must not contain false or misleading
A drug must not be an imitation or offered under the name of another drug.

Containers for drugs must not be so made and filled as to be deceptive.

**COSMETICS**

**HEALTH GUARDS**

A cosmetic must not contain any substance which may make it harmful to users when used as is customary or under the directions for use indicated in the labeling.

Dangerous coal-tar hair dyes must be labeled with the caution statement stipulated in the Act.

Cosmetic containers must not be composed of any substance which may render the contents harmful.

Cosmetics (except hair dyes) may contain only those coal-tar colors which come from a batch certified as being harmless.

**SANITATION**

A cosmetic must not consist of any filthy, putrid or decomposed substance.

Cosmetics must be prepared, packed, and held under sanitary conditions.

**LABELING INFORMATION**

Cosmetic labeling must include the following information:

1. The name and address of the manufacturer, packer or distributor.
2. An accurate statement of the quantity of contents.
3. All the information required by the Act must be shown in the labeling in a form easily noticed and readily understood.

**PROHIBITED DECEPTIONS**

The labeling of a cosmetic must not be false or misleading in any particular.
A cosmetic container must not be so made, formed, or filled as to be misleading.

DEVICES

HEALTH GUARD

A device must not be dangerous to health when used with the frequency or duration prescribed in the labeling.

PROHIBITED DECEPTION

The labeling of a device must not be false or misleading in any particular.

LABELING INFORMATION

The labeling of a device must contain the following information:

1. An accurate statement of the quantity of contents.
2. The name and address of the manufacturer, packer or distributor.
3. Adequate directions for use.
4. Warnings against unsafe use by children.
5. Warnings against uses which may be dangerous to health.
6. All the information required by the Act must be shown in the labeling in a form easily noticed and readily understood.1

1 "Consumer Protection," United States Food and Drug Administration, 1941.
FEDERAL SECURITY AGENCY
FOOD AND DRUG ADMINISTRATION
SERVICE AND REGULATORY ANNOUNCEMENTS
Food, Drug, and Cosmetic No. 1
Revision 2

FEDERAL FOOD, DRUG, AND COSMETIC ACT AND GENERAL REGULATIONS FOR ITS ENFORCEMENT

INTRODUCTION

This publication contains an unofficial print of the Federal Food, Drug, and Cosmetic Act, as amended, and general regulations, as amended, for its administration. The second revision incorporates all changes made in the Act and general regulations since printing of the first revision in August 1941. The section numbers of the regulations printed herein are the same as those used in Title 21, Chapter 1, of the Code of Federal Regulations. Footnote references are made to certain regulations authorized by the Act that are not reprinted in this publication.

MAURICE COLLINS
Acting Federal Security Administrator

February 15, 1946.
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AN ACT

To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

General Regulation. [§ 2.1] (a) The provisions of regulations promulgated under the Act with respect to the doing of any act shall be applicable also to the causing of such act to be done.
(b) The definitions and interpretations of terms contained in section 201 of the Act shall be applicable also to such terms when used in regulations promulgated under the Act.

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—
(a) The term “Territory” means any Territory or possession of the United States, including the District of Columbia and excluding the Canal Zone.
(b) The term “interstate commerce” means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.
(c) The term “Agency” means the Federal Security Agency.
(d) The term “Administrator” means the Federal Security Administrator.
(e) The term “person” includes individual, partnership, corporation, and association.
(f) The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.
(g) The term “drug” means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (8) articles (other than food) intended to affect the structure or any function of the body of man or other animals;
and (4) articles intended for use as a component of any articles specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(h) The term “device” (except when used in paragraph (n) of this section and in sections 301 (i), 403 (f), 502 (c), and 602 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term “cosmetic” means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term “official compendium” means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term “label” means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term “immediate container” does not include package liners.

(m) The term “labeling” means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Regulation. [§ 22] Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

[Sec. 201. For the purposes of this Act—]

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

Regulation. [§ 28] The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.
For the purposes of this Act—

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Regulation. [§ 2.108] Newness of a drug may arise by reason (among other reasons) of:

(a) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component;

(b) The newness for drug use of a combination of two or more substances, none of which is a new drug;

(c) The newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug;

(d) The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body; or

(e) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

Sec. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

(e) The refusal to permit access to or copying of any record as required by section 703.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (e) (3), which guaranty or undertaking is false.

Regulation. [§ 2.4] In case of the giving of a guaranty or undertaking referred to in section 303 (c) (2) or (3) of the Act, each person signing such guaranty or undertaking shall be considered to have given it.

[Sec. 301. The following acts and the causing thereof are hereby prohibited:] (i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404, 406 (b), 504, 506, 507, or 604.

(j) The using by any person to his own advantage, or revealing, other than to the Administrator or officers or employees of the Agency, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 505, or 704 concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 505, or that such drug complies with the provisions of such section.

INJUNCTION PROCEEDINGS

Sec. 302. (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes," approved October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (e), (f), (h), (i), and (j).

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this
Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 387).

**PENALTIES**

**Sec. 303.** (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Administrator the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Administrator under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Administrator under this Act.

**Régulation.** [§ 2.5] (a) A guaranty or undertaking referred to in section 303 (c) (2) of the Act may be:

1. limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or
2. general and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been
given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303 (c) (2) of the Act:

(1) Limited Form for use on invoice or bill of sale.

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404 or 505 of the Act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and Continuing Form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or on the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Act, or becomes an article which may not, under the provisions of section 404 or 505 of the Act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(c) The application of a guaranty or undertaking referred to in section 303 (c) (2) of the Act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the Act, or becomes an article which may not, under the provisions of section 404 or 505 of the Act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303 (c) (3) of the Act shall state that the shipment or other delivery of coal-tar color covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303 (c) (3) of the Act:

(1) For domestic manufacturers.

(Name of manufacturer) hereby guarantees that all coal-tar colors listed herein were manufactured by him, and are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(2) For foreign manufacturers.

(Name of manufacturer and agent) hereby severally guarantee that all coal-tar colors listed herein were manufactured by (name of manufacturer), and are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(Signature and post-office address of agent.)

(f) For the purpose of a guaranty or undertaking under section 303 (c) (3) of the Act the manufacturer of a shipment or other delivery of a coal-tar color is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the Act shall be made in labeling.

SEIZURE

Sec. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, under the provisions of section
404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: Provided, however, That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (2) when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial.

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.
(c) The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized, and as regards fresh fruits or fresh vegetables, a true copy of the analysis on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: Provided, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Administrator; and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

(e) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) In the case of removal for trial of any case as provided by subsection (a) or (b)—

1. The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

2. The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

HEARING BEFORE REPORT OF CRIMINAL VIOLATION

Sec. 305. Before any violation of this Act is reported by the Administrator to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

Regulation. [§ 2.6] (a) Presentation of views under section 305 of the Act shall be private and informal. The views presented shall be confined to matters relat-
want to the contemplated proceeding. Such views may be presented by letter or in person by the person to whom the notice was given, or by his representative. In case such person holds a guaranty or undertaking referred to in section 303 (c) (2) or (3) of the Act applicable to the article on which such notice was based, such guaranty or undertaking, or a verified copy thereof, shall be made a part of such presentation of views.

(b) Upon request, seasonably made, by the person to whom a notice appointing a time and place for the presentation of views under section 305 of the Act has been given, or by his representative, such time or place, or both such time and place, may be changed if the request states reasonable grounds therefor. Such request shall be addressed to the office of the Food and Drug Administration which issued the notice.

REPORT OF MINOR VIOLATIONS

Sec. 306. Nothing in this Act shall be construed as requiring the Administrator to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

PROCEEDINGS IN NAME OF UNITED STATES; PROVISION AS TO SUBPENAS

Sec. 307. All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Notwithstanding the provisions of section 876 of the Revised Statutes, subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

Sec. 401. Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: Provided, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Administrator shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which

1 Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 2.
optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Administrator for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: Provided, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Administrator, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: Provided, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.
MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

Regulation. [§ 2.7] (a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

[SEC. 408. A food shall be deemed to be misbranded—]

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Administrator.

Regulation. [§ 2.8] (a) Where a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such food, such as "Manufactured for and Packed by __________ ; Distributed by __________ ," or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such food was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any food from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of food in the package, exclusive of wrappers and other material packed with such food.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such food and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such food exists, the statement shall be in terms of liquid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and, except in case of frozen food which is so
consumed, shall express the volume at 68° Fahrenheit (20° Centigrade). A statement of dry measure shall be in terms of the United States bushel of 2150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof; or in terms of the United States standard barrel and its subdivisions of third, half, and three-quarters barrel. However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported.

(2) A statement of weight or measure in the terms specified in subparagraph (1) of this paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of food in the package, it shall be supplemented by such statement of weight, measure, or size of the individual units of the food as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of the food. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of food in the package equals or exceeds the smallest unit of weight or measure which is specified in paragraph (f) of this section, and which is applicable to such food under the provisions of paragraph (e) (2) of this section, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one quart of food shall be “1 quart,” and not “2 pints” or “32 fluid ounces”), unless the statement is made in accordance with the provisions of subparagraph (2) of this paragraph. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for example, 1 1/2 quarts may be expressed as “1 quart 1 1/2 pints” or “1 quart 1 pint 8 fluid ounces”; 1 1/4 pounds may be expressed as “1 pound 4 ounces”). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for example, instead of “1 quart 16 fluid ounces” the statement shall be “1 1/2 quarts” or “1 quart 1 pint”; instead of “24 ounces” the statement shall be “1 1/4 pounds” or “1 pound 8 ounces”).

(2) In the case of a food with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity:

(1) variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packing practice.
But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the food is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(1) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A food shall be exempt from compliance with the requirements of clause (2) of section 403 (e) of the Act if:

1. The quantity of the contents, as expressed in terms applicable to such food under the provisions of paragraph (e) (2) of this section, is less than one-half ounce avoirdupois, or less than one-half fluid ounce, or (in case the units of the food can be easily counted without opening the package) less than six units; or

2. The statement of the quantity of the contents of the package, together with all other words, statements, and information required by or under authority of the Act to appear on the label, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 403 (f) of the Act and regulations promulgated thereunder.

SEC. 403. A food shall be deemed to be misbranded—

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Regulation, [§ 2.9] (a) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by section 403 (f) of the Act by reason (among other reasons) of:

1. The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

2. The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

3. The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

4. Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

5. Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

6. Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 403 (e) or (f) of the Act, shall apply if such insufficiency is caused by:

1. The use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;
(2) The use of label space, to give greater conspicuousness to any word, statement, or other information than is required by section 403 (f) of the Act; or

(3) The use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

[Sec. 403. A food shall be deemed to be misbranded—]

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

Regulation. [§2.14] In the following conditions, among others, a food does not conform to the definition and standard of identity therefor:

(a) If it contains an ingredient for which no provision is made in such definition and standard;

(b) If it fails to contain any one or more ingredients required by such definition and standard;

(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard.

[Sec. 403. A food shall be deemed misbranded—]

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: Provided, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Administrator.

Regulation. [§ 2.10] (a) The name of an ingredient (except a spice, flavoring, or coloring which is an ingredient of a food other than one sold as a spice, flavoring, or coloring), required by section 403 (1) (2) of the Act to be borne
on the label of a food, shall be a specific name and not a collective name. But if an ingredient (which itself contains two or more ingredients) conforms to a definition and standard of identity prescribed by regulations under section 401 of the Act, such ingredient may be designated on the label of such food by the name specified in the definition and standard, supplemented, in case such regulations require the naming of optional ingredients present in such ingredient, by a statement showing the optional ingredients which are present in such ingredient.

(b) No ingredient shall be designated on the label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be, within the meaning of such term as commonly understood by consumers. The term "coloring" shall not include any bleaching substance.

(c) An ingredient which is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as spice and coloring, or flavoring and coloring, as the case may be, unless such ingredient is designated by its specific name.

(d) A label may be misleading by reason (among other reasons) of:

(1) The order in which the names of ingredients appear thereon, or the relative prominence otherwise given such names; or

(2) Its failure to reveal the proportion of, or other fact with respect to, an ingredient, when such proportion or other fact is material in the light of the representation that such ingredient was used in fabricating the food.

(e) (1) A food shall be exempt from the requirements of clause (2) of section 403 (1) of the Act if all words, statements, and other information required by or under authority of the Act to appear on the label of such food, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 403 (f) of the Act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (2), such statement of the quantity of the contents shall be omitted as authorized by § 2.9 (m) (2), and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) In the case of an assortment of different items of food, when variations in the items which make up different packages packed from such assortment normally occur in good packing practice, and when such variations result in variations in the ingredients in different packages, such food shall be exempt from compliance with the requirements of clause (2) of section 403 (1) of the Act with respect to any ingredient which is not common to all packages. But such exemption shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement in terms which are as informative as practicable and which are not misleading, indicating that other ingredients may be present.

[Sec. 403. A food shall be deemed to be misbranded—]

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Administrator determines to be, and by regulations prescribing as, necessary in order fully to inform purchasers as to its value for such uses.

Regulation. (§ 2.11) (a) The term “special dietary uses”, as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(1) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but

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not limited to the conditions of disease, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(2) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(3) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

(b) No provision of any regulation under section 403 (j) of the Act shall be construed as exempting any food from any other provision of the Act or regulations thereunder, including sections 403 (a) and (g) and, when applicable, the provisions of Chapter V.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: Provided, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

**Regulation.** [§ 2.12] (a) The term "artificial flavoring" means a flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

(2) The term "artificial coloring" means a coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

(3) The term "chemical preservative" means any chemical which, when added to food, tends to prevent or retard deterioration thereof; but does not include common salt, sugars, vinegars, spices or oils extracted from spices, or substances added to food by direct exposure thereof to wood smoke.

(b) A food which is subject to the requirements of section 403 (k) of the Act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food.

(d) A food shall be exempt from compliance with the requirements of section 403 (k) of the Act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

**EMERGENCY PERMIT CONTROL**

Sec. 404. (a) Whenever the Administrator finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or
packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Administrator as provided by such regulations.

(b) The Administrator is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Administrator shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Any officer or employee duly designated by the Administrator shall have access to any factory or establishment, the operator of which holds a permit from the Administrator, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

REGULATIONS MAKING EXEMPTIONS

Sec. 405. The Administrator shall promulgate regulations exempting from any labeling requirement of this Act (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

Regulation. [§ 2.13] (a) (1) An open container is a container of rigid or semirigid construction, which is not closed by lid, wrapper, or otherwise.

(2) An open container of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than one dry quart, shall be exempt from the labeling requirements of paragraphs (e), (g) (2) (with respect to the name of the food specified in the definition and standard), and (1) (1) of section 403 of the Act; but such exemption shall be on the condition that if two or more such containers are enclosed in a crate or other shipping package, such crate or package shall bear labeling showing the number of such containers enclosed therein and the quantity of the contents of each.

(b) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (1), (j) and (k) of the Act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or
(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will insure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Agency who requests them.

(c) An exemption of a shipment or other delivery of a food under paragraph (b) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(d) An exemption of a shipment or other delivery of a food under paragraph (b) (2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such paragraph.

(e) An exemption of a shipment or other delivery of a food under paragraph (b) (2) of this section shall expire:

1. At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

2. Upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such paragraph.

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

Sec. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Administrator shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Administrator shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Administrator shall promulgate regulations providing for

*21 CFR, 1944 Supp., 120.1 et seq; 9 F. R. 11836.
the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.

CHAPTER V—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—
(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Administrator, insufficient for the making of such determination, the Administrator shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Administrator, are sufficient for purposes of this paragraph, then the Administrator shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

Regulation. [§ 2.100] (a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

4 Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 3.
(b) The term "drug defined in an official compendium" means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.

[Sec. 501. A drug or device shall be deemed to be adulterated—]

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

MISBRANDED DRUGS AND DEVICES

Sec. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

Regulation. [§ 2.101] (a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic.

(b) The labeling of a drug which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

Sec. 502. A drug or device shall be deemed to be misbranded—

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Administrator.

Regulation. [§ 2.102] (a) If a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such drug or device, such as "Manufactured for and Packed by ________", "Distributed by ________", or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs, or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any drug or device from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents of a package of a drug shall reveal the quantity of such drug in the package, exclusive of wrappers and other material packed with such drug.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers and users of such drug to express quantity thereof and which give accurate information as to such quantity. But if no general usage in expressing accurate
information as to the quantity of such drug exists among consumers and users thereof, the statement of the quantity of a drug which is not in tablet, capsule, ampul, or other unit form shall be in terms of weight if the drug is solid, of weight or measure if the drug is liquid; the statement of the quantity of a drug which is in such unit form shall be in terms of the numerical count of such units, supplemented, when necessary to give accurate information as to the quantity of such drug in the package, by such statement (in such terms, manner, and form as are not misleading) of the weight or measure of such units, or of the quantity of each active ingredient in each such unit, as will give such information.

(8) The statement of the quantity of a device shall be expressed in terms of numerical count.

(f) A statement of weight shall be in terms of the avoirdupois pound, ounce, and grain, or of the kilogram, gram, and milligram. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, fluid ounce, and fluid dram subdivisions thereof, or of the liter, milliliter, or cubic centimeter, and shall express the volume at 68° Fahrenheit (20° Centigrade).

(g) Statements of the quantity of a drug shall contain only such fractions as are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(h) (1) Unless made in accordance with the provisions of subparagraph (2) of this paragraph, a statement of the quantity of a drug, in the terms of weight or measure applicable to such drug under the provisions of paragraph (e) (2) of this section, shall express the number of the largest unit specified in paragraph (f) of this section which is contained in the package (for example, the statement of the label of a package containing one pint of a drug shall be “1 pint,” and not “16 fluid ounces”). Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for example, 1 1/4 pounds may be expressed as “1 pound 4 ounces”). The stated number of any unit which is smaller than the largest unit specified in such paragraph (f) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for example, instead of “1 quart 16 fluid ounces” the statement shall be “1 1/2 quarts” or “1 quart 1 pint”).

(2) In the case of a drug with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(1) The statement of the quantity of a drug or device shall express the minimum quantity, or the average quantity, of the contents of the package. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement, except in the case of ampuls, shall be considered to express the average quantity. The statement of the quantity of a drug in ampuls shall be considered to express the minimum quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except vagiations below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large. In the case of a liquid drug in ampuls the variation above the stated measure shall comply with the excess volume prescribed by the National Formulary for filling of ampuls.

(k) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure of a drug shall be permitted when caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which nor-
mally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) Variations from the stated weight, measure, or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting the contents of individual packages which occur in good packing practice. But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the drug or device is below the quantity stated and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(1) The extent of variations from the stated quantity of the contents permissible under subparagraphs (j) and (k) of this regulation in the case of each shipment or other delivery shall be determined by the facts in each case.

(m) A drug or device shall be exempt from compliance with the requirements of clause (2) of section 502 (b) of the Act if:

(1) The statement of the quantity of the contents, as expressed in terms applicable to such drug or device under the provisions of paragraph (e) (2) of this section, together with all other words, statements, and information required by or under authority of the Act to appear on the label of such drug or device, cannot, because of insufficient label space, be placed on the label as to comply with the requirements of section 502 (a) of the Act and regulations promulgated thereunder or

(2) The quantity of the contents of the package, as expressed in terms of numerical count in compliance with paragraph (e) (2) or (3) of this section, is less than six units, and such units can be easily counted without opening the package.

[Sec. 502. A drug or device shall be deemed to be misbranded—]

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Regulation. [§2.103] (a) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by section 502 (c) of the Act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 502 (b) or (e) of the Act, shall apply if such insufficiency is caused by:
(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502 (c) of the Act; or

(3) The use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

[Sec. 502. A drug or device shall be deemed to be misbranded—]

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, beta-euaine, bromal, cannabis, carboxomal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethylene; or any chemical derivative of such substance, which derivative has been by the Administrator, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement “Warning—May be habit forming”.

Regulation. [§ 2.104] (a) (1) The name of a substance or derivative required to be borne on the label of a drug by section 502 (d) of the Act shall be the common or usual name of such substance or derivative, unless it is designated solely by a name recognized in an official compendium and such designation complies with the provisions of section 502 (c).

(2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in section 502 (d) of the Act, shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(c) The names and quantities or proportions of all such substances and derivatives, and the statement “Warning—May be habit forming,” shall immediately follow (without intervening written, printed, or graphic matter) the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded by reason of failure of its label to bear the statement “Warning—May be habit forming”:

(1) If such drug is not suitable for internal use, and is distributed and sold exclusively for such external use as involves no possibility of habit formation; or

(2) If the only substance or derivative subject to section 502 (d) of the Act contained in such drug is chlorobutanol, which is present solely as a preservative and in a quantity not more than 0.5 percent by weight, and such drug is for parenteral use only; or

(3) If the only substance or derivative subject to section 502 (d) of the Act contained in such drug is chlorobutanol, which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 3.0 percent, and such drug contains one or more other active ingredients and is for parenteral use only.

(SEc. 502. A drug or device shall be deemed to be misbranded—]

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetaldehyde, acetylsalicylic acid, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: Provided, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator.

Regulation. [§ 2.105] (a) (1) The name of an ingredient, substance, derivative, or preparation required by section 502 (e) (2) of the Act to be borne on the label of a drug shall be the name thereof, which is listed in such section 502 (e) (2) of the Act, or, if not so listed, shall be a specific name and not a collective name. But if an ingredient is an article the name of which is recognized in an official compendium and such article complies with the specifications set forth therefor in such compendium, such ingredient may be designated on the label of such drug by the common or usual name under which such specifications are so set forth.

(2) Where an ingredient contains a substance the quantity or proportion of which is required by section 502 (e) (2) of the Act to appear on the label, and such ingredient is not a derivative or preparation of such substance as defined in paragraph (b) (1) of this section, the label shall bear, in conjunction with the name of the ingredient, a statement of the quantity or proportion of such substance in such drug.

(3) An abbreviation or chemical formula shall not be considered to be a common or usual name. The name "acacetophenetidin" shall be considered to be the same as the name "acetphenetidin," "aminopyrine" the same as "amidopyrine." The name "alcohol" without qualification, means ethyl alcohol.

(b) (1) A derivative or preparation of a substance named in section 502 (e) (2) of the Act is an article which is derived or prepared from such substance by any method, including actual or theoretical chemical action.

(2) A statement on the label of a drug of the name of an ingredient thereof, which ingredient is a derivative or preparation of a substance named in section 502 (e) (2) of the Act, shall show the substance from which such ingredient is derived or prepared and that such ingredient is a derivative or preparation thereof.

(e) (1) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of a substance, derivative, or preparation contained therein shall express the weight or measure of such substance, derivative, or preparation in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance, derivative, or preparation in a specified unit of weight or measure of the drug, or the percentage of such substance, derivative, or preparation in such drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(2) A statement of the percentage of alcohol shall express the percentage of absolute alcohol at 60° Fahrenheit (15.56° Centigrade). A state-
ment of the percentage of a substance, derivative, or preparation other than alcohol shall express the percentage by weight; except that if both the substance, derivative, or preparation and the drug containing it are liquid, the statement may express the percentage by volume at 68° Fahrenheit (20° Centigrade), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(d) In case a statement of the quantity or proportion of a derivative or preparation in a drug is not as informative, to consumers or users of such drug, of the activity or consequences of use thereof as a statement of the quantity or proportion of the substance from which such derivative or preparation is derived or prepared, the quantity or proportion of such substance shall also be stated on the label of such drug.

(e) A label of a drug may be misleading by reason (among other reasons) of:

(1) The order in which the names of ingredients, substances, derivatives, or preparations appear thereon, or the relative prominence otherwise given such names; or

(2) Its failure to reveal the proportion of, or other fact with respect to, an ingredient, substance, derivative, or preparation, when such proportion or other fact is material in the light of the representation that such ingredient, substance, derivative, or preparation is a constituent of such drug.

(f) (1) A drug shall be exempt from the requirements of clause (2) of section 502 (e) of the Act if all words, statements, and other information required by or under authority of the Act to appear on the label of such drug, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 502 (c) of the Act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (2), such statement of the quantity of the contents shall be omitted as authorized by § 2.102 (m) (1), and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) A drug shall be exempt from the requirements of clause (2) of section 502 (e) of the Act with respect to the alkaloids atropine, hyoscine or hyoscyamine contained in such drug, if such alkaloid is contained therein as a constituent of belladonna, hyoscyamus, scopola, stramonium, or other plant material, or any preparation thereof, which was used as an ingredient of such drug, and no practical and accurate method of analysis exists for the quantitative determination of each such alkaloid in such ingredient. But such exemption shall be on the condition that the label of such drug shall state the quantity or proportion of total alkaloids contained therein as constituents of such ingredient.

[Sec. 502. A drug or device shall be deemed to be misbranded—]

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement.

Régulation. [§2.106] (a) Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part, or incorrect specification of:
(1) Directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any there be, for which such drug or device is commonly and effectively used;

(2) Quantity of dose (including quantities for persons of different ages and different physical conditions);

(3) Frequency of administration or application;

(4) Duration of administration or application;

(5) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factor);

(6) Route or method of administration or application; or

(7) Preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

(b) Except as otherwise provided by paragraphs (h) and (i) of this section, a shipment or other delivery of a drug or device shall be exempt from the requirements of section 502 (f) (1) of the Act if it complies with all of the following conditions:

(1) Such drug or device, because of its toxicity or other potentiality for harmful effect or the method of its use or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy, as safe and efficacious for use except by or under the supervision of a physician, dentist, or veterinarian.

(2) Such shipment or delivery is to be:

(i) Dispensed by physicians, dentists, or veterinarians in their professional practice;

(ii) Dispensed upon prescriptions issued by physicians, dentists, or veterinarians in their professional practice and under labeling bearing the directions for use specified in such prescriptions;

(iii) Compounded with other substances in filling such prescriptions; or

(iv) Used in the manufacture of another drug or device.

(8) Information adequate for the use of such drug or device by physicians, dentists, or veterinarians, as the case may be, is readily available.

(4) The label of such drug or device (other than surgical instruments and other devices to be used exclusively by physicians, dentists, or veterinarians in their professional practice) bears the statement "Caution: To be dispensed only by or on the prescription of a ________", or "Caution: To be dispensed only by or on the prescription of a ________ or otherwise used only for manufacturing purposes", the blank being filled in with one or more of the words "physician", "dentist", and "veterinarian", as the case may be.

(5) No representation with respect to the conditions for which a drug or device is to be used, or how it is to be used, appears in its labeling except representations:

(1) In printed matter supplied to a physician, dentist, or veterinarian separately from such drug or device;

(2) Specified in a prescription, which was issued by a physician, dentist, or veterinarian in his professional practice, upon which such drug or device was dispensed; or

(3) Required by an official compendium.

(6) In the case of a drug which is not designated solely by a name recognized in an official compendium and which is fabricated from two or more ingredients, its label also bears a statement of the quantity or proportion of each active ingredient.

(c) Except as otherwise provided by paragraphs (h) and (i) of this section, a shipment or other delivery of a drug which cannot be exempted under paragraph (b) of this regulation because of the provisions of subparagraph (1) thereof also shall be exempt from the requirements of section 502 (f) (1) of the Act if it complies with all of the conditions set forth in paragraph (b) (4) and (5) of this section and with all of the following additional conditions:
(1) Such drug is not a liquid solution, emulsion, or suspension and is not in tablet, capsule, or other unit form.

(2) The name whereby such drug is designated in its label is recognized in an official compendium.

(3) Such drug is ordinarily compounded with other substances before it is dispensed.

(4) Such shipment or delivery is to be:
   (i) Compounded with other substances in filling prescriptions issued by physicians, dentists, or veterinarians in their professional practice; or
   (ii) Used in the manufacture of another drug.

(d) Except as otherwise provided by paragraphs (h) and (i) of this section, a shipment or other delivery of a drug which cannot be exempted under paragraph (b) of this section because of the provisions of subparagraph (1) thereof also shall be exempt from the requirements of section 502 (f) (1) of the Act if it is ordinarily used as an inactive ingredient, such as a coloring, emulsifier, excipient, flavoring, lubricant, preservative, or solvent, of other drugs.

(e) Except as otherwise provided by paragraphs (h) and (i) of this section, a shipment or other delivery of a drug or device also shall be exempt from the requirements of section 502 (f) (1) of the Act if it complies with all the conditions set forth in paragraphs (b) (3) and (6) of this section and if such shipment or delivery is made to a physician, dentist, veterinarian, hospital, or clinic to be dispensed by or under the direction of physicians, dentists, or veterinarians in their professional practice.

(f) A shipment or other delivery of a drug or device also shall be exempt from the requirements of section 502 (f) (1) of the Act if it is made to a dealer or manufacturer to be used in the manufacture of another drug or device and its label bears the statement "For manufacturing use only."

(g) A shipment or other delivery of a drug or device also shall be exempt from the requirements of section 502 (f) (1) of the Act with respect to common uses, adequate directions for which are known by the ordinary individual.

(h) No shipment or other delivery of any drug shall be exempt under any provision of this section from any requirement of section 502 (f) (1) of the Act unless its labeling bears the information concerning its use which is contained in the labeling upon the basis of which an application under section 505 of the Act is effective with respect to such drug.

(i) No exemption under any provisions of this regulation shall apply to any shipment or other delivery of:
   (1) A drug if its advertising disseminated or sponsored by or on behalf of its manufacturer, packer, or other person responsible for making such shipment or delivery, contains any representation not borne by its labeling and which, if so borne, would make it a new drug;

   (2) A drug intended for administration by iontophoresis or by injection into or through the skin or mucous membrane; or

   (3) A drug or device if such shipment or delivery is made in the course of the conduct of a business of dispensing drugs or devices pursuant to diagnosis by mail.

(j) If a shipment or other delivery, or any part thereof, of a drug or device which is exempt under paragraph (b), (c), (e), or (f) of this section is disposed of for any purpose other than those specified in such paragraph, such exemption shall expire, with respect to such shipment or delivery or part thereof which is so disposed of, at the beginning of the act of such disposal. The causing of an exemption so to expire shall be considered to be an act which results in such drug or device being misbranded unless, prior to such disposal, it is relabeled to comply with the requirements of section 502 (f) (1) of the Act, or it is disposed of for use otherwise than as a drug or device.

(k) For the purposes of this section:
   (1) The term "manufacture" does not include the use of a drug as an ingredient in compounding any prescription issued by a physician, dentist, or veterinarian in his professional practice.

   (2) The terms "physician", "dentist", and "veterinarian", as used in relation to the exemption of any drug or device, include only those physicians, dentists, and veterinarians who are licensed by law to administer or apply such drug or device.
[Sec. 502. A drug or device shall be deemed to be misbranded—]

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: Provided, That the method of packing may be modified with the consent of the Administrator. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia.

(h) If it has been found by the Administrator to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Administrator shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Administrator shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(k) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 506, and (2) such certificate or release is in effect with respect to such drug.

Regulation. [§ 2.115] For the purposes of sections 502 (k) and 506 of the Act, the term "insulin" as used therein means the active principle of pancreas which affects the metabolism of carbohydrate in the animal body and which is of value in the treatment of diabetes mellitus.

(1) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507, and (2) such certificate or release is in effect with respect to such drug: Provided, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507 (c) or (d).

EXEMPTIONS IN CASE OF DRUGS AND DEVICES

Sec. 503. (a) The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or
packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

**Regulation. [§ 2.107]** (a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501 (b) and 502 (b), (d), (e), (f), and (g) of the Act if:

1. The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or

2. In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Agency who requests them.

(b) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(c) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such subparagraph.

(d) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (2) of this section shall expire:

1. At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

2. Upon refusal by the operator of the establishment where such drug or device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

(e) Except as provided in paragraphs (g) and (h) of this section, a shipment or other delivery of a drug which is subject to section 507 of the Act and which is, in accordance with the practice of the trade, to be processed or repacked in a substantial quantity at an establishment other than that where originally processed or packed shall be exempt from compliance with the labeling requirements of section 502 (f) of the Act during the time such drug is also exempt from the requirements of section 502 (1) of the Act under the provisions of § 146.20 or 146.21 of this chapter.

(f) Except as provided by paragraphs (g) and (h) of this section, a shipment or other delivery of a drug which is subject to section 507 of the Act and which is, in accordance with the practice of the trade, to be labeled in substantial quantity at an establishment other than that where originally processed or packed shall be exempt from compliance with the labeling requirements of section 502 (b), (e) and (f) of the Act during the time such drug is also exempt from the requirements of section 502 (1) of the Act under § 146.18 of this chapter, if the words, statements, and other information required by section 502 (b) and (e) of the Act appear on each shipping container of such drug.
(g) In case the person who introduced such shipment or other delivery into interstate commerce is the operator of the establishment where such drug is to be processed, labeled, or repacked, an exemption of such shipment or delivery under paragraph (e) or (f) of this section shall become void ab initio at the beginning of the act of removing such shipment or delivery or any part thereof from such establishment if the drug comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(h) In case the person who introduced such shipment or delivery into interstate commerce is not the operator of the establishment where such drug is to be processed, labeled, or repacked, an exemption of a shipment or other delivery of such drug under paragraph (e) or (f) of this section shall expire at the beginning of the act of removing such shipment or delivery or any part thereof from such establishment if the drug comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

[Sec. 503] (b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), shall if—

(1) such physician, dentist, or veterinarian is licensed by law to administer such drug; and

(2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian,

be exempt from the requirements of section 502 (b) and (e), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of section 502 (d).

CERTIFICATION OF COAL-TAR COLORS FOR DRUGS

Sec. 504. The Administrator shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for the certification of batches of such colors, with or without harmless diluents.

NEW DRUGS

Sec. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

Regulation. [§ 2.109] A new drug shall not be deemed to be subject to section 505 of the Act if it is a drug which is licensed under the Virus, Serum, and Toxin Act of July 1, 1902, (32 Stat. 723; 42 U. S. C. 151-158), or the Virus, Serums, Toxins, Antitoxins and Analogous Products Act of March 4, 1913 (52 Stat. 1052; 21 U. S. C. 855 (a)).

[Sec. 505] (b) Any person may file with the Administrator an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Administrator as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, process-

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ning, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Administrator may require; and (6) specimens of the labeling proposed to be used for such drug.

Regulation. [§ 2.110] (a) Each application submitted for filing with the Administrator shall be in duplicate. If any part of the application is in a foreign language, an accurate and complete English translation shall be appended to such part.

(b) An application shall not be accepted for filing if only one copy is submitted or if it is incomplete on its face in that:

(1) It does not contain all the matter required by clauses (1), (2), (3), (4), and (6) of section 505 (b) of the Act;

(2) It does not state the conditions under which the drug is to be used; or

(3) The specimens of labeling proposed for use upon or within the retail package do not expressly or by reference to a brochure or other printed matter prescribe, recommend, or suggest the use of such drug under such conditions.

The Food and Drug Administration shall notify the applicant of such non-acceptance and the reason therefor and, in case of incompleteness as to matter required by any clause of section 505 (b), shall specify such clause. Otherwise the date on which an application is received by the Agency shall be considered to be the date on which such application is filed, and the Food and Drug Administration shall notify the applicant of such date. If the applicant withdraws his application, such application shall be considered as not having been filed.

(c) The applicant may file an amendment to an application which has been filed and is pending before the Administrator, but in such case the unamended application shall be considered as having been withdrawn and the amended application shall be considered as having been filed on the date on which the amendment is received by the Agency. The Food and Drug Administration shall notify the applicant of such date.

(d) After an application has become effective with respect to a drug, the applicant may file a supplemental application with respect thereto, setting forth any proposed change in the conditions, under which such drug is to be used, in the labeling thereof, in any circumstance relating to its production, or in any other information contained in the effective application. Such supplemental application may omit statements made in the effective application concerning which no change is proposed.

[Sec. 505] (c) An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Administrator by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Administrator deems necessary to enable him to study and investigate the application.

Regulation. [§ 2.111]. If the Administrator determines, before the date prescribed by section 505 (c) of the Act for an application to become effective, that he has no cause to issue an order under section 505 (d) of the Act refusing to permit such application to become effective, the Food and Drug Administration shall so notify the applicant in writing and such application shall become effective on the date of the notification.

[Sec. 505] (d) If the Administrator finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Administrator pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the re-
results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

**Regulation.** [§ 2.112]. The information contained in an application may be insufficient for the Administrator to determine whether a drug is safe for use if it fails to include (among other things) a statement showing whether the drug is to be exempt under any provision of regulation § 2.106, as amended, promulgated pursuant to section 502 (f) of the Act, from the requirement that its labeling bear adequate directions for use. If the drug is to be so exempt, the information may also be insufficient if:

1. The specimen label of the drug fails to incorporate by reference a specifically identified brochure or other printed matter containing information adequate for the use of such drug by physicians, dentists, or veterinarians, as the case may be;
2. Such label fails to state that the drug is to be used as shown in such brochure or printed matter and that such brochure or printed matter will be sent to physicians, dentists, or veterinarians, as the case may be, on request;
3. The application fails to contain copies of such brochure or printed matter; or
4. The application fails to show that such brochure or printed matter is readily available to physicians, dentists, or veterinarians, as the case may be, or, if not, that it is to be made so when the application becomes effective.

**Regulation.** [§ 2.113]. Among the reasons why an application may contain an untrue statement of a material fact are changes in:

1. Conditions of use prescribed, recommended, or suggested by the applicant for the drug from the conditions of such use stated in the application;
2. Articles used as components of the drug from those listed in the application;
3. Composition of the drug from that stated in the application;
4. Methods used in, or the facilities or controls used for, the manufacture, processing, or packing of the drug from such methods, facilities, and controls described in the application; and
5. Labeling from the specimens contained in the application.

**Regulation.** [§ 2.113]. An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Administrator finds that the facts so require.

**Regulation.** [§ 2.113]. Orders of the Administrator issued under this section shall
be served (1) in person by any officer or employee of the Agency designated by the Administrator or (2) by mailing the order by registered mail addressed to the applicant or respondent at his last-known address in the records of the Administrator.

(h) An appeal may be taken by the applicant from an order of the Administrator refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his principal place of business, or in the District Court of the United States for the District of Columbia, within sixty days after the entry of such order, a written petition praying that the order of the Administrator be set aside. A copy of such petition shall be forthwith served upon the Administrator, or upon any officer designated by him for that purpose, and thereupon the Administrator shall certify and file in the court a transcript of the record upon which the order complained of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Administrator shall be considered by the court unless such objection shall have been urged before the Administrator or unless there were reasonable grounds for failure so to do. The finding of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Administrator, the court may order such additional evidence to be taken before the Administrator and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Administrator may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Administrator shall be final, subject to review as provided in sections 128, 239, and 240 of the Judicial Code, as amended (U. S. C., 1934 ed., title 28, secs. 225, 346, and 347), and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia", approved February 9, 1893 (D. C. Code, title 18, sec. 26). The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Administrator's order.

(i) The Administrator shall promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs.

Regulation. [§ 2.114] (a) A shipment or other delivery of a new drug shall be exempt from the operation of section 505 (a) of the Act if all of the following requirements are complied with:

(1) The label of such drug shall bear the statement "Caution: New drug—Limited by Federal law to investigational use".
(2) Such shipment or delivery shall be made only to, and solely for investigational use by or under the direction of, an expert qualified by scientific training and experience to investigate the safety of such drug.

(3) The person who introduced such shipment or delivery into interstate commerce shall keep complete records showing the date and quantity of each such shipment and delivery.

(4) Such person, prior to making such shipment or delivery, shall obtain a statement signed by such expert showing that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation, unless and until an application becomes effective with respect to such drug under section 505 of the Act. Such person shall keep such statement.

(5) Such person shall make all documents referred to in subparagraphs (3) and (4) available for inspection upon the request of any officer or employee of the Agency at any reasonable hour until three years after the introduction of such shipment or delivery into interstate commerce.

(b) An exemption of a shipment or other delivery of a new drug under paragraph (a) of this section shall become void ab initio if:

(1) The person who introduced such shipment or delivery into interstate commerce fails to keep any document required to be kept by such paragraph; or

(2) Such person fails to make any such document available for inspection, as required by such paragraph.

(c) An exemption of a shipment or other delivery of a new drug under paragraph (a) of this section shall expire upon the use of any part of such shipment or delivery other than in accordance with the signed statement referred to in (4) of such paragraph.

CERTIFICATION OF DRUGS CONTAINING INSULIN

Sec. 506. (a) The Federal Security Administrator, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of insulin. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Administrator prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Administrator, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

(b) Regulations providing for such certification shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe no standard of identity or of strength, quality, or purity for any drug different from the standard of identity, strength, quality, or purity set forth for such drug in an official compendium.

(c) Such regulations, insofar as they prescribe tests or methods of assay to determine strength, quality, or purity of any drug, different from the tests or methods of assay set forth for such drug in an official compendium, shall be prescribed, after notice and opportunity for revision of such compendium, in the manner provided in the second sentence of section 501 (b). The provisions of subsections (e), (f), and (g) of section 701 shall be applicable to such portion of any regulation as prescribes any such different test or method, but shall not be applicable to any other portion of any such regulation.

CERTIFICATION OF DRUGS CONTAINING PENICILLIN

SEC. 507. (a) The Federal Security Administrator, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin or any derivative thereof. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Administrator prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Administrator, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

(b) Regulations providing for such certifications shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe only such tests and methods of assay as will provide for certification or rejection within the shortest time consistent with the purposes of this section.

(c) Whenever in the judgment of the Administrator, the requirements of this section and of section 502 (1) with respect to any drug or class of drugs are not necessary to insure safety and efficacy of use, the Administrator shall promulgate regulations exempting such drug or class of drugs from such requirements.

(d) The Administrator shall promulgate regulations exempting from any requirement of this section and of section 502 (1), (1) drugs which are to be stored, processed, labeled, or repacked at establishments other than those where manufactured, on condition that such drugs comply with all such requirements upon removal from such establishments; (2) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed by these regulations.

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and are intended for use in manufacturing other drugs; and (3) drugs which are intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs.

(e) No drug which is subject to section 507 shall be deemed to be subject to any provision of section 505. Compliance of any drug subject to section 502 (1) or 507 with sections 501 (b) and 502 (g) shall be determined by the application of the standards of strength, quality, and purity, the tests and methods of assay, and the requirements of packaging and labeling, respectively, prescribed by regulations promulgated under section 507.

(f) Any interested person may file with the Administrator a petition proposing the issuance, amendment, or repeal of any regulation contemplated by this section. The petition shall set forth the proposal in general terms and shall state reasonable grounds therefor. The Administrator shall give public notice of the proposal and an opportunity for all interested persons to present their views thereon, orally or in writing, and as soon as practicable thereafter shall make public his action upon such proposal. At any time prior to the thirtieth day after such action is made public any interested person may file objections to such action, specifying with particularity the changes desired, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Administrator shall thereupon, after due notice, hold such public hearing. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action on such objections. The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. The order shall be subject to the provisions of section 701 (f) and (g).

CHAPTER VI—COSMETICS

ADULTERATED COSMETICS

Sec. 601. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: Provided, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: “Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness,”; and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term “hair dye” shall not include eyelash dyes or eyebrow dyes.

Regulation. [§ 2.200] The term “coal-tar hair dye” includes all articles containing any coal-tar color or intermediate which color or intermediate alters the color of the hair when such articles are applied to the hair under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.
[Sec. 601. (b)] A cosmetic shall be deemed to be adulterated—
(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.
(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604.

MISBRANDED COSMETICS

Sec. 602. A cosmetic shall be deemed to be misbranded—
(a) If its labeling is false or misleading in any particular.

Regulation. [§ 2.201] (a) Among representations in the labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug, or device.
(b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

Sec. 602. A cosmetic shall be deemed to be misbranded—
(b) In package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Administrator.

Regulation. [§ 2.202] (a) If a cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such cosmetic such as “Manufactured for and Packed by _________”, “Distributed by _________”, or other similar phrase which expresses the facts.
(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.
(c) Where a person manufactures, packs, or distributes a cosmetic at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such cosmetic was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.
(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any cosmetic from the requirement that its label shall not be misleading in any particular.
(e) (1) The statement of the quantity of the contents shall reveal the quantity of cosmetic in the package, exclusive of wrappers and other material packed with such cosmetic.
(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such cosmetic and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate
Information as to the quantity of such cosmetic exists, the statement shall be in terms of liquid measure if the cosmetic is liquid, or in terms of weight if the cosmetic is solid, semisolid, or viscous, or in such terms of numerical count, or numerical count and weight or measure, as will give accurate information as to the quantity of the cosmetic in the package.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of 281 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and shall express the volume at 68° Fahrenheit (20° Centigrade). However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported.

(2) A statement of weight or measure in the terms specified in subparagraph (1) of this paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(8) Unless an unqualified statement of numerical count gives accurate information as to the quantity of cosmetic in the package, it shall be supplemented by such statement of weight, measure, or size of the individual units of the cosmetic as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of the cosmetic. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of cosmetic in the package equals or exceeds the smallest unit of weight or measure which is specified in paragraph (f) of this section, and which is applicable to such cosmetic under the provisions of paragraph (e) (2) of this section, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one pint of cosmetic shall be "1 pint" and not "16 fluid ounces"), unless the statement is made in accordance with the provisions of subparagraph (2) of this paragraph. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for example, 1¾ quarts may be expressed as "1 quart 1½ pints" or "1 quart 1 pint 8 fluid ounces"; 1½ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not exceed the number of such smaller units in the next larger unit so specified (for example, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1½ pounds" or "1 pound 8 ounces").

(2) In the case of a cosmetic with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(1) The statement shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(f) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the cosmetic is intro-
duced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure.

(2) Variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packing practice. But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the cosmetic is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(1) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A cosmetic shall be exempt from compliance with the requirements of clause (2) of section 602 (b) of the Act if the quantity of the contents of the package, as expressed in terms applicable to such cosmetic under the provisions of paragraph (e) (2) of this section, is less than one-fourth ounce avoirdupois, or less than one-eighth fluid ounce, or (in case the units of the cosmetic can be easily counted without opening the package) less than six units.

[Sec. 602. A cosmetic shall be deemed to be misbranded—]

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Regulation. [§ 2.203] (a) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by section 602 (c) of the Act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device;

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.
(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

[SEC. 602. A cosmetic shall be deemed to be misbranded—]

(d) If its container is so made, formed, or filled as to be misleading.

REGULATIONS MAKING EXEMPTIONS

SEC. 603. The Administrator shall promulgate regulations exempting from any labeling requirement of this Act cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

Regulation. [§ 2.204] (a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a cosmetic which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of sections 601 (a) and 602 (b) of the Act if:

1. The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such cosmetic is to be processed, labeled, or repacked; or

2. In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling or repacking, as the case may be, of such cosmetic in such establishment as will insure, if such specifications are followed, that such cosmetic will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Agency who requests them.

(b) An exemption of a shipment or other delivery of a cosmetic under paragraph (a) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(c) An exemption of a shipment or other delivery of a cosmetic under paragraph (a) (2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such clause.

(d) An exemption of a shipment or other delivery of a cosmetic under paragraph (a) (2) of this section shall expire:

1. At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

2. Upon refusal by the operator of the establishment where such cosmetic is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.
CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS

Sec. 604. The Administrator shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

Sec. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Administrator.

(b) The Secretary of the Treasury and the Federal Security Administrator shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Federal Security Administrator shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Administrator or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) The Administrator, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Administrator shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Administrator, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Administrator finds that emergency conditions exist necess-

4 Service and Regulatory Announcements, Food, Drug, and Cosmetic No. 3.
sitting an earlier effective date, then the Administrator shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Administrator shall specify therein to meet the emergency.

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. The summons and petition may be served at any place in the United States. The Administrator, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Administrator based his order.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Administrator, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Administrator, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Administrator may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Administrator refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Administrator to take action, with respect to such regulation, in accordance with law. The findings of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Administrator shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Administrator or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Administrator to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to
this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

EXAMINATIONS AND INVESTIGATIONS

Sec. 702. (a) The Administrator is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Agency or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Administrator as an officer of the Agency. In the case of food packed in a Territory the Administrator shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this Act, the facilities at his disposal will permit of such inspection. For the purposes of this subsection the term “United States” means the States and the District of Columbia.

(b) Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Administrator shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Administrator is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

Regulation. [§ 2.700] (a) (1) When any officer or employee of the Agency collects a sample of a food, drug, or cosmetic for analysis under the Act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Agency indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory. Only samples so designated by an officer or employee of the Agency shall be considered to be official samples.

(2) For the purpose of determining whether or not a sample is collected for analysis, the term “analysis” includes examinations and tests.

(3) The owner of a food, drug, or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

(b) When an officer or employee of the Agency collects an official sample of a food, drug, or cosmetic for analysis under the Act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless:

(1) The amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated;

(2) The cost of twice the quantity so estimated exceeds $10;

(3) The article is perishable;

(4) The sample is collected from a shipment or other lot which is being imported or offered for import into the United States;

(5) The sample is collected from a person named on the label of the article, or his agent, and such person is also the owner of the article;

(6) The sample is collected from the owner of the article, or his agent, and such article bears no label or, if it bears a label, no person is named thereon; or

(7) The analysis consists principally of rapid analytical procedures, organoleptic examination, or other field inspection examinations or tests.

For Sec. 702 A, sea-food inspection provisions, see footnote 12, p. 56.
made at the place where the sample is collected or in a mobile or temporary laboratory.

In addition to the quantity of sample prescribed above the officer or employee shall, if practicable, collect as part of the sample such further amount of the article as he estimates to be sufficient for use as exhibits in the trial of any case that may arise under the Act based on the sample.

(c) After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the Act, or otherwise subject to the prohibitions of the Act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the Act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, except when:

(1) After collection, the sample or remaining part thereof has become decomposed or otherwise unfit for analysis, or
(2) The request is not made within a reasonable time before the trial of any case under the Act, based on the sample, to which such person or owner is a party.

The person, owner, attorney, or agent who requests the part of sample shall specify the amount desired. A request from an owner shall be accompanied by a showing of ownership, and a request from an attorney or agent by a showing of authority from such person or owner to receive the part of sample. When two or more requests for parts of the same sample are received the requests shall be complied with in the order in which they were received so long as any part of the sample remains available therefor.

(d) When an official sample of a food, drug, or cosmetic is the basis of a notice given under section 805 of the Act, or of a case under the Act, and the person to whom the notice was given, or any person who is a party to the case, has no right under paragraph (c) of this section to a part of the sample, such person or his attorney or agent may obtain a part of the sample upon request accompanied by a written waiver of right under such paragraph (c) from each person named on the label of the article and owner thereof, who has not exercised his right under such paragraph (c). The operation of this paragraph shall be subject to the exceptions, terms, and conditions prescribed in paragraph (c) of this section.

(e) The Food and Drug Administration is authorized to destroy:

(1) Any official sample when it determines that no analysis of such sample will be made;
(2) Any official sample or part thereof when it determines that no notice under section 805 of the Act, and no case under the Act, is or will be based on such sample;
(3) Any official sample or part thereof when the sample was the basis of a notice under section 805 of the Act, and when, after opportunity for presentation of views following such notice, it determines that no other such notice, and no case under the Act, is or will be based on such sample;
(4) Any official sample or part thereof when the sample was the basis of a case under the Act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample;
(5) Any official sample or part thereof if the article is perishable;
(6) Any official sample or part thereof when, after collection, such sample or part has become decomposed or otherwise unfit for analysis;
(7) That part of any official sample which is in excess of three times the quantity it estimates to be sufficient for analysis.

[Sec. 702] (c) For purposes of enforcement of this Act, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Federal Security Agency duly authorized by the Administrator to make such inspection.
RECORDS OF INTERSTATE SHIPMENT

Sec. 703. For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Administrator, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: Provided, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: Provided further, That carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

FACTORY INSPECTION

Sec. 704. For purposes of enforcement of this Act, officers or employees duly designated by the Administrator, after first making request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter, at reasonable times; any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

PUBLICITY

Sec. 705. (a) The Administrator shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Administrator may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Administrator, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Administrator from collecting, reporting, and illustrating the results of the investigations of the Agency.

COST OF CERTIFICATION OF COAL-TAR COLORS

Sec. 706. The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this Act, shall be
performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

CHAPTER VIII—IMPORTS AND EXPORTS

Sec. 801. (a) The Secretary of the Treasury shall deliver to the Federal Security Administrator, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Federal Security Administrator and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission. This paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under section 2 of the Act of May 26, 1922, as amended (U.S.C., 1934 edition, title 21, sec. 173).

(b) The Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any such article refused admission, unless such article is exported by the consignee within three months from the date of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe: Provided, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter or execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon and on refusing for any cause to return such article or any part thereof to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose, such consignee shall forfeit the full amount of the bond as liquidated damages.

Regulation. [§ 2.300] Shipper’s declaration. A person who ships a food, drug, device, or cosmetic to the United States shall make a declaration (on Form No. 197 or No. 198 Consular, whichever shall be applicable) which shall include a statement to the effect that such article has not been manufactured, processed, or packed under insanitary conditions; that such article is not forbidden or restricted in sale in the country in which it was produced or from which it was exported; that such article is not adulterated, misbranded nor in violation of section 505 of the Act.

FORM NO. 198—CONSULAR* DECLARATION OF SHIPPER OF FOOD, DRUG, AND COSMETIC PRODUCTS

Regarding shipment covered by Invoice No. __________, certified at ____________ on ____________, I, the undersigned, am the _______ of seller or owner) (Seller or owner, or agent of seller or owner)

*Consular Form 197 contains the same wording—but in addition includes a special invoice (form) at the bottom of the sheet. (It is employed in cases where the usual consular invoice is not required.)
paying consular invoice. It consists of food, drug, or cosmetic products (or devices as defined by the Federal Food, Drug, and Cosmetic Act) which contain no added substance injurious to health. These products were grown

______ and manufactured in ________________ by ___________.

(Country) (Town and country) (Name of manufacturer)

during the year _______ and are exported from _______ and con-

(Signature) (City)

signed to __________________________. They contain no false labels or marks, contain no added coloring matter except ___________ except _________.

(State coloring matter used, if any)

no preservative (salt, sugar, vinegar, or wood smoke excepted) except ___________.

(State pres-

servative used, if any)

I further declare that such article or articles are not of such character as to prohibit their entry into the United States in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act in that they have not been manufactured, processed, or packed under insanitary conditions, nor are they of a character to cause prohibition or restriction in sale in the country where made or from which exported, nor are they adulterated or misbranded, nor are they in violation of section 505 of the Federal Food, Drug, and Cosmetic Act.

I further declare that the drug products herein mentioned and described contain no opium, coca leaves, cocaine, or any salt, derivative or preparation of opium, coca leaves, or cocaine, the importation of which into the United States is prohibited by the Narcotic Drugs Import and Export Act, as amended.

I do solemnly and truly declare the foregoing statements to be true, to the best of my knowledge and belief.

Dated at __________________________ this ________ day of _______________________

(Signature) __________________________ (Month and year)

INSTRUCTIONS TO CONSULAR OFFICERS

§ 2.301 (a) (1) This declaration (§ 2.300) is to be firmly attached to all copies of consular invoices covering shipments of over $100 in value.

(2) The official seal must be placed on the declaration, and the number, date of certification of invoice, and name of post plainly indicated.

(3) Shipper should be instructed to declare the name of the manufacturer whenever possible.

(4) If the declaration is believed to be incorrect or incomplete, or if consul believes that the goods are liable to detention, he should note such information on the invoice in the consular corrections or remarks column.

(b) If the article is to be offered for import at Atlanta, Baltimore, Boston, Buffalo, Chicago, Cincinnati, Denver, Houston, Kansas City, Los Angeles, Minneapolis, New Orleans, New York, Philadelphia, San Francisco, St. Louis, Seattle, or other port where a station shall be established by the Food and Drug Administration, the seller or shipper shall attach such declaration to the invoice on which such article is to be entered.

(c) If the article is to be offered for import at a port where no station has been established by the Food and Drug Administration, the seller or shipper shall make an extra copy of such invoice for the station of the Food and Drug Administration within the jurisdiction of which such port is located, and shall attach such declaration to such extra copy.

§ 2.302 (a) Bonds—delivery—sampling. No food, drug, device, or cosmetic shall be delivered to the consignee prior to report of examination of such article, or prior to the stamping of the invoice as prescribed by paragraph (b) of this section showing that no sample is desired, except upon the execution on the appropriate form of a customs single-entry or term bond, containing a condition for the redelivery of the merchandise, or any part thereof, upon demand of the collector of customs at any time, in such amount as is prescribed for such bonds in the customs regulations in force on the date of entry. The bond shall be filed with the collector of customs, who, in case of default, shall take appropriate action to effect the collection of liquidated damages provided for in the bond.

(b) As soon as the importer makes entry of an article, the invoice covering it and the package of it designated by the collector of customs for examination
shall be made available, with the least possible delay, for inspection by a representative of the station. When a sample is desired the representative shall request the collector of customs or the appropriate customs officer therefor, indicating the size of the sample. When no sample is desired the invoice shall be stamped by the representative "No sample desired. Food and Drug Administration, Federal Security Agency, per (initials of the representative)."

(c) (1) At ports of entry where there is no laboratory of the Food and Drug Administration the collector of customs or appropriate customs officer shall, on the day of receipt of the first notice, by invoice or entry, of an expected shipment of article subject to the Act, notify the chief of station, within whose territory the port is located, of the expected shipment.

(2) If no sample is desired, the chief of station, on the day he receives the notice, shall advise the collector of customs or appropriate customs officer by mail to that effect. Such advice shall be equivalent to stamping invoices at ports where stations are located with the statement prescribed in paragraph (b) of this section.

(3) If a sample is desired, the chief of station shall immediately request the collector of customs or appropriate customs officer to forward it and indicate the size of sample.

(4) Upon receipt of such request the collector of customs or appropriate customs officer shall forward the sample without delay, together with a description of the shipment.

(5) When samples will be desired from each shipment of a particular article or when samples will not be desired, the chief of station shall furnish, at least every 6 months, to collectors of customs or appropriate customs officers within the station territory, a list of such articles and on the list of articles of which samples will be desired, shall indicate the size of sample for each such article. Upon the arrival of shipments of articles appearing on the list of samples which will be desired, the collectors of customs or appropriate customs officers shall send such samples to the station without delay, together with a description of the shipments. The list of articles, samples of which will not be requested, shall be treated as the equivalent of paragraph (b) of this section and the invoices of such articles shall be handled accordingly.

(6) In all particulars the procedure shall be the same at non-laboratory ports as at laboratory ports except that the time consumed in delivery by mail of the notice of hearing shall be allowed for.

[§ 2.303] Jurisdiction. (a) Whether or not an article, is in compliance with or in violation of the provisions of section 801 of the Act is to be determined by the officers of the stations of the Food and Drug Administration.

(b) The detention, exportation, and destruction of merchandise shall be accomplished under customs supervision. At laboratory ports customs officers and officers of the Food and Drug Administration may alternately, in accordance with local agreement, perform duties, or supervise operations, under §§ 2.300-2.312, which are not specifically assigned to either service, consideration being given to local conditions and personnel.

(c) At non-laboratory ports the collector of customs or appropriate customs officer shall carry out the necessary operations on receipt of the necessary information from the chief of station of the Food and Drug Administration of the appropriate laboratory port.

[§ 2.304] Notices required under Sec. 801 of the Act. All notices required by regulation under section 801 of the Act to be given to the owner or consignee of an article offered for import shall be deemed to have been duly and effectively given if given to the importer of record of such article.

[§ 2.305] Notice of sampling. (a) A notice to an owner or consignee that a sample of an article has been requested by the Federal Security Administrator shall be in writing and shall be mailed by the collector of customs or appropriate customs officer to such owner or consignee, or such notice may be given by a suitable bulletin notice posted in the custom house listing all invoices of articles from which samples will be taken and posted in the custom house not later than 1 day after the day the decision is reached to take samples from such articles. Such bulletin notice shall remain posted for 1 week.
(b) The notice to an owner or consignee that a sample of an article has been requested by the Federal Security Administrator shall likewise state that such article must be held intact until released.

§ 2.306 Release; No violation detected. If it does not appear from the examination of the sample or otherwise that an article is adulterated, misbranded or in any other respect subject to prohibitions of the Act, the chief of station of the Food and Drug Administration shall give written notice of release to the owner or consignee of such article and a copy thereof shall be sent to the collector of customs or appropriate customs officer.

§ 2.307 Procedure when violation is alleged. (a) If the result of the examination of the sample or other evidence indicates that an article is adulterated, misbranded, or otherwise subject to the prohibitions of the Act, the chief of station of the Food and Drug Administration shall give written notice thereof to the owner or consignee of such article and a copy thereof shall be sent to the collector of customs or appropriate customs officer. Such notice shall allege the respects in which such article appears to be adulterated, misbranded, or otherwise subject to the prohibitions of the Act, and shall set a time and place for such owner or consignee to appear and introduce testimony.

(b) Such testimony shall be confined to matters relevant to the alleged adulteration, misbranding or other condition subject to the prohibitions of the Act, and may be introduced by letter or in person by such owner or consignee, or by a representative chosen by him for the purpose.

(c) Upon request, seasonably made, by such owner, consignee, or representative, such time may be changed if the request states reasonable grounds therefor and is made on or prior to the date for the hearing. Such request shall be addressed to the chief of station of the Food and Drug Administration which issued the notice.

§ 2.308 Procedure after hearing; release or rejection and notice. (a) After the owner or consignee of an article appears, produces testimony, or is given reasonable opportunity therefor, as provided by § 2.307 (b), the chief of station of the Food and Drug Administration, over the signature of the collector of customs or authorized stamped facsimile thereof, shall notify such owner or consignee in writing that such article is released so far as the Act is concerned, and send a carbon copy of the notice to the collector of customs or appropriate customs officer, or so notify such owner or consignee, that it appears from such examination that such article does not conform with the provisions of the Act, and that it is to be refused admission, stating the reason therefor in such notice and send a carbon copy of the notice to the collector of customs or appropriate customs officer.

(b) The notice of refusal of admission shall state that the article must be exported or destroyed under customs supervision within 3 months of the date thereof, as provided by law. The owner or consignee (or importer of record in case notice has been sent to him) shall return the notice to the collector of customs or appropriate customs officer with the information required by the form filled in and properly certified. The copy of the notice sent to the collector of customs by the chief of station, when action is completed, shall then be returned to the chief of station with notation thereon of the action taken. The exportation of articles refused admission under the Act or the regulations thereunder shall be in accordance with the procedure set forth in the applicable customs regulations which have been or may be prescribed by the Secretary of the Treasury.

§ 2.309 Relabeling or other act to bring article into compliance with the Act and notice. (a) The owner or consignee of an article may, at the time of the hearing or within a reasonable time thereafter, request the chief of station of the Food and Drug Administration in writing to permit the relabeling or other act with respect to such article necessary to bring it into compliance with the provisions of the Act, or to render it not a food, drug, device, or cosmetic within the meaning of the definitions of such articles in section 201 (f), (g), (h), and (i) of the Act. Such request shall propose the labeling to be used and any other act to be done for such purpose, and shall specify the time and place where such proposed labeling or other act is to be done.

(b) Unless such relabeling or other act with respect to such article is prohibited by paragraph (c) of this section, the chief of station of the Food and Drug Administration, over the signature of the collector of customs or au-
authorized stamped facsimile thereof, will give such owner or consignee written notice that such relabelling or other act will be permitted, and send a carbon copy of the notice to the collector of customs.

Such notice shall specify all conditions which must be fulfilled within 3 months of the date of the notice in order to bring such article into compliance with the provisions of the Act including the destruction, under customs supervision, of all rejected material, or to render it not a food, drug, device, or cosmetic within the meaning of the definitions of such articles in section 201 (f), (g), (h), and (i) of the Act, and to bring the performance thereof within the provisions of the bond covering the merchandise.

In addition, the notice shall also indicate the officer who shall be notified by the owner or consignee (or the importer of record if notice has been sent to him) when the operations have been completed and the article is ready for inspection. If such conditions are fulfilled within 3 months of the date of the notice specified by this paragraph, such article will be released, and notice thereof given to the owner or consignee. A carbon copy of the notice shall be sent to the collector of customs.

(c) When it appears that the labelling constitutes a flagrant or intentional misbranding, or that the condition of the article is such as to indicate deliberate adulteration, or the owner or consignee thereof was informed with respect to any violation prior to the date of export, or that a public notice had been issued by the Federal Security Administrator to the effect that, after a date prior to such date of export, such relabelling or other act with respect to such article would not be permitted, then the provisions of the preceding paragraphs shall not apply and the article must be destroyed or exported under customs supervision.

(d) When relabelling or other act with respect to such article is to be allowed under the provision of paragraph (b) of this section, the owner or consignee (or importer of record if the notice has been sent to him) shall return the notice to the collector of customs, or the appropriate customs officer, or chief of station designated thereon, with the certificate on the notice filled out stating that he has performed the prescribed operations, that the rejected portion required to be held for destruction is so held and is ready for destruction under customs supervision, that the article, including such rejected portion, is ready for inspection, naming the place where such article and such portion are held.

(e) The officer so notified shall deliver the notice to the representative of the Food and Drug Administration or to the appropriate customs officer who is to make the inspection. After inspection the representative shall write a report thereof on the back of the notice and send it to the collector of customs, or the appropriate customs officer, or chief of station, as the case may be, from whom he received the notice.

§ 2.310 Release of detained goods which have been reconditioned.

(a) (1) When the operations to be performed are under the entire supervision of the chief of the station, and these operations have been effectively and completely performed and all of the conditions imposed have been fulfilled within the time prescribed therefor, he shall give notice to the importer that the article is released insofar as the provisions of the Act relate thereto and shall send a copy thereof to the collector of customs or the appropriate customs officer; but if the operations have not been effectively and completely performed, and all of the conditions imposed, have not been fulfilled within the time prescribed therefor, and the article is to be exported or destroyed, the chief of station, over the signature of the collector of customs, or authorized stamped facsimile thereof, shall immediately give notice of refusal of admission to the importer and shall send a carbon thereof to the collector of customs or the appropriate customs officer. Such notice shall show that the article must be exported or destroyed, under customs supervision, within 3 months from the date of notice, as required by law.

(2) When, however, the operations to be performed are under the supervision of the chief of station and the destruction of a rejected portion of the article under customs supervision is a condition of the release, the chief of station shall give notice to the collector of customs or the appropriate customs officer that the portion which has been brought
into compliance with the Act is ready for release after destruction of the rejected portion has been accomplished, under customs supervision, and transmit to him the notice received from the importer with the form thereon properly filled in showing that the rejected portion is ready for destruction. The collector of customs or the appropriate customs officer, with the least possible delay, shall supervise the destruction of the rejected portion. Within 1 day after such destruction the collector of customs or the appropriate customs officer shall return such notice to the chief of station after having noted thereon that the destruction has been accomplished. Within 1 day after the receipt of such notice the chief of station shall send notice of release of the article to the importer and a carbon copy thereof to the collector of customs or appropriate customs officer.

(b) When all the operations to be performed are under customs supervision, and these operations have been effectively and completely performed within the time prescribed therefor, the collector of customs or the appropriate customs officer shall give the notice of release of the article to the owner or consignee and shall send a carbon copy thereof to the chief of station. If the conditions imposed include destruction of the rejected portion of the article no release of the article shall be given until the rejected portion has been destroyed under customs supervision. If, however, operations have not been effectively and completely performed within the time prescribed therefor, the collector of customs or appropriate customs officer shall give notice to the owner or consignee that the article shall be exported or destroyed within 3 months from the date of the notice and shall send a copy thereof to the chief of station.

(c) The privilege of relabeling or other operation to bring an article into compliance with the Act shall be allowed only when the owner or consignee agrees to hold the article at a stated place and to maintain conditions at all times which will preserve the identity of the article and prevent its loss through mixture with other articles or otherwise. The owner or consignee shall furnish evidence satisfactory to the chief of station or collector of customs or appropriate customs officer by affidavit or otherwise as to the identity of any article which has been subject to such operations.

(d) When the collector of customs or the appropriate customs officer has taken final action with respect to an article which has been refused admission, or with respect to which relabeling or other operations have been permitted under his supervision he shall give notice thereof to the chief of station, showing the date of release or destruction, or the date of exportation and the country to which the article is exported, as the case may be.

(e) The chief of station may require that the owner or consignee submit affidavits executed before a Notary Public or other officer authorized to administer oaths generally, showing to the satisfaction of the chief of station the use to which such article has been put.

(f) Inspection of articles under the Act involving relabeling and other operations to bring them into compliance with the Act when no representative of the station is available therefor, and inspection of articles to be exported or destroyed, in whole or in part, shall be performed by collectors of customs or the appropriate customs officers.

(g) Collectors of customs and chiefs of stations shall make joint arrangement for the apportionment of inspection duties between them, due regard being given to local conditions. Whenever feasible representatives of stations at laboratory ports shall inspect articles which have been relabeled or subjected to other operations to bring them in compliance with the Act. At non-laboratory ports relabeling and other operations will be under the supervision of the collector of customs or the appropriate customs officer.

§ 2.311 Disposal in violation of the Act, regulations or bond. (a) If a customs officer who has supervision over the disposal of an article acquires evidence tending to show that the disposal was in violation of the Act or of §§ 2.300 and 2.310 or of the terms of the bond, the collector of customs or appropriate customs officer shall immediately send such evidence in detail to the chief of station. The chief of station shall send to the collector of customs or the appropriate customs officer a statement giving a summary of all the facts and any additional evidence which he may have tending to show the importers' liability under the bond.
(b) If the chief of the station has supervision over the disposal of an article and acquires evidence that the disposal was in violation of the Act or this part, or of the terms of the bond, he shall immediately send to the collector of customs or the appropriate customs officer a statement giving a summary of all the facts and any evidence he may have tending to show the importers' liability under the bond.

(c) The collector of customs or the appropriate customs officer, within 3 days of receipt of the statement and evidence, shall notify the owner or consignee that the article must be returned to customs custody. If the article is not returned to customs custody within 30 days from the date of the notice, action shall be taken immediately to enforce the terms of the bond unless, in the meantime, the owner or consignee shall file with the collector of customs or the appropriate customs officer an application for cancellation of the liability incurred under the bond upon the payment as liquidated damages of a lesser amount than the full amount of the liquidate damages incurred, or upon the basis of such other terms and conditions as the Secretary of the Treasury may deem sufficient. The application shall contain a full statement of the reasons for the requested cancellation and shall be in duplicate and under oath.

(d) The collector of customs or the appropriate customs officer shall transmit the application, his recommendation, and the station chief's statement, all in duplicate, to the Secretary of the Treasury, through the Bureau of Customs, for the necessary action.

(e) All notices required by regulation under section 801 of the Act to be given to the owner or consignee of an article offered for import shall be deemed to have been duly and effectively given if given to the importer of record of such article.

§ 2.312 Article suitable only for technical or restricted use, denaturing. (a) A food, drug, or cosmetic which is adulterated or misbranded within the meaning of this Act and which is offered for import for industrial purposes must be denatured and the invoice thereof must bear a statement showing that the article is to be used for industrial purposes.

Where, however, it is impracticable to denature such article it may be permitted entry, Provided:

(1) It is plainly and conspicuously labeled, in the case of food, "inedible," and, in the case of drugs, "not for medicinal use."

(2) At the time of entry the owner or ultimate consignee submits a statement in writing that the article will not be used as a food, drug, or cosmetic.

(3) At the time of entry the owner or ultimate consignee submits a statement that the article will be used in a certain suitable manner by a certain named party or parties.

(4) At the time of entry the owner or ultimate consignee agrees to furnish satisfactory proof as to the actual use of the article and the name or names of the parties who use it.

The liability under the bond given at the time of entry will not be regarded as having been satisfied until such evidence of satisfactory disposition shall have been received by the collector of customs.

(b) A food, drug, or cosmetic having but a restricted legitimate use and of such character that it can not legally be distributed for unrestricted general use, e. g., pharmacopoeial crude drugs deficient in active principle and certain substitutes for pharmacopoeial crude drugs, may be allowed entry if properly labeled, provided suitable evidence be furnished by affidavit or otherwise that it will be used by a designated party or parties for manufacture into articles in which it may be legitimately employed. The liability under the bond given at the time of entry will not be regarded as having been satisfied until proof of satisfactory use of the product shall have been received by the collector of customs.

[Sec. 801.] (c) All charges for storage, cartage, and labor on any article which is refused admission or delivery shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignee.

(d) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it
(1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act.

CHAPTER IX—MISCELLANEOUS

SEPARABILITY CLAUSE

Sec. 901. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

EFFECTIVE DATE AND REPEALS

Sec. 902. (a) This Act shall take effect twelve months after the date of its enactment. ¹ The Federal Food and Drugs Act of June 30, 1906, as amended (U. S. C., 1934 ed., title 21, secs. 1-15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: Provided, That the provisions of section 701 shall become effective on the enactment of this Act, and thereafter the Secretary [of Agriculture] is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary [of Agriculture] shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403 (i) for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401: Provided further, That sections 502 (j), 505, and 601 (a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section 601 (a) relates, such cosmetic shall not, prior to the ninetieth day after such date of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: Provided further, That the Act of March 4, 1923 ¹⁰ (U. S. C., 1934 ed., title 21, sec. 6; 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 ¹¹

¹ The Act of June 23, 1939 (see p. 57), temporarily postponed the operation of certain provisions until January 1, 1940, and July 1, 1940.

¹⁰ That for the purposes of the Food and Drug Act of June 30, 1906 (Thirty-fourth Statutes at Large, page 768), “butter” shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 percentum by weight of milk fat, all tolerances having been allowed for.

¹¹ That the word “package” where it occurs the second and last time in the Act entitled “An act to amend section 8 of an act entitled, “An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous

(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended (U. S. C., 1934 ed., title 21, secs. 71–91; 34 Stat. 1260 et seq.).


(d) In order to carry out the provisions of this Act which take effect prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended, is amended to read as follows:

Sec. 10A. The Federal Security Administrator, upon application of any packer of any sea food for shipment or sale within the jurisdiction of this Act; may, at his discretion, designate inspectors to examine and inspect such food and the production, packing, and labeling thereof. If on such examination and inspection compliance is found with the provisions of this Act and regulations promulgated thereunder, the applicant shall be authorized or required to mark the food as provided by regulation to show such compliance. Services under this section shall be rendered only upon payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service. Receipts from such fees shall be covered into the Treasury and shall be available to the Federal Security Administrator for expenditures incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. The Administrator is hereby authorized to promulgate regulations governing the sanitary and other conditions under which the service herein provided shall be granted and maintained and for otherwise carrying out the purposes of this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than $1,000 nor more than $5,000 or both such imprisonment and fine.


Section 902 (d)  -  Federal Food, Drug, and Cosmetic Act

1906, as amended, appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions.

(Approved June 25, 1938.)

PUBLIC—NO. 151—76TH CONGRESS

AN ACT

To provide for temporary postponement of the operations of certain provisions of the Federal Food, Drug, and Cosmetic Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That (a) the effective date of the following provisions of the Federal Food, Drug, and Cosmetic Act is hereby postponed until January 1, 1940: Sections 402 (c); 403 (e) (1); 403 (g), (h), (i), (j), and (k); 501 (a) (4); 502 (b), (d), (e), (f), (g), and (h); 601 (e); and 602 (b).

(b) The Secretary of Agriculture shall promulgate regulations further postponing to July 1, 1940, the effective date of the provisions of sections 403 (e) (1); 403 (g), (h), (i), (j), and (k); 502 (b), (d), (e), (f), (g), and (h), and 602 (b) of such Act with respect to lithographed labeling which was manufactured prior to February 1, 1939, and to containers bearing labeling which, prior to February 1, 1939, was lithographed, etched, stamped, pressed, printed, fused or blown on or in such containers, where compliance with such provisions would be unduly burdensome by reason of causing the loss of valuable stocks of such labeling or containers, and where such postponement would not prevent the public interest being adequately served: Provided, That in no case shall such regulations apply to labeling which would not have complied with the requirements of the Food and Drugs Act of June 30, 1906, as amended.

Sec. 2 (a) The provisions of section 8, paragraph fifth, under the heading “In the case of food:” of the Food and Drugs Act of June 30, 1906, as amended, and regulations promulgated thereunder, and all other provisions of such Act to the extent that they may relate to the enforcement of such section 8 and of such regulations, shall remain in force until January 1, 1940.

(b) The provisions of such Act of June 30, 1906, as amended, to the extent that they impose, or authorize the imposition of, any requirement imposed by section 502 (k) of the Federal Food, Drug, and Cosmetic Act, shall remain in force until January 1, 1940.

(c) Notwithstanding the provisions of section 1 of this Act, such section shall not apply—

(1) to the provisions of section 502 (d) and (e) of the Federal Food, Drug, and Cosmetic Act, insofar as such provisions relate to any substance named in section 8, paragraph second, under the heading “In the case of drugs:”, of the Food and Drugs Act of June 30, 1906, as amended, or a derivative of any such substance; or

(2) to the provisions of section 502 (b), (d), (e), (f), (g), and (h) of the Federal Food, Drug, and Cosmetic Act, insofar as such provisions relate to drugs to which section 505 of such Act applies.
Sec. 8. Section 502 (d) of the Federal Food, Drug, and Cosmetic Act is hereby amended by striking out the words "name, quantity, and percentage" where they appear therein and substituting in lieu thereof "name, and quantity or proportion".

Approved June 23, 1939.