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OTC Brand Name Extensions

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OTC Brand Name Extensions

Some Selected Nonprescription Product Lines	Expected Primary Ingredient	Actual Primary Ingredients
Examples of U.S. Brand Name Extensions		
Alka-Seltzer[4,5]	Aspirin	There are many different *Alka-Seltzer* products. *Alka-Seltzer Original, Lemon Lime,* and *Extra Strength* all contain aspirin. *Alka-Seltzer Morning Relief* contains *aspirin* plus *caffeine. Alka-Seltzer PM* contains aspirin plus diphenhydramine. The following products contain acetaminophen with other ingredients but no aspirin: *Alka-Seltzer Plus Cold Effervescent Tablets* and *Liqui-Gels, Alka-Seltzer Plus Cold & Sinus, Alka-Seltzer Plus Night-Time Cold Effervescent Tablets* and *Liqui-Gels, Alka-Seltzer Plus Cold and Cough Liqui-Gels,* and *Alka-Seltzer Plus Nose and Throat.*. These products contain no aspirin or acetaminophen: *Alka-Seltzer Gold, Alka-Seltzer Heartburn Relief,* and *Alka-Seltzer Plus Cold & Cough Effervescent Tablets.*
Allerest[5]	Chlorpheniramine	*Allerest No-Drowsiness* contains pseudoephedrine and acetaminophen without chlorpheniramine.
Anacin[5]	Aspirin	*Anacin Aspirin Free Extra Strength* contains acetaminophen instead of aspirin.
Betadine[5]	Povidone-iodine	*Betadine Antibiotics Plus Moisturizer* contains polymyxin and bacitracin. *Betadine Plus Antibiotics & Pain Reliever Ointment* contains polymyxin, bacitracin, and pramoxine.
Bufferin[5]	Aspirin	*Bufferin AF Nite Time* contains acetaminophen and diphenhydramine.
Comtrex[5]	Chlorpheniramine	*Comtrex Maximum Strength Non-Drowsy Cold and Cough* does not contain an antihistamine.
Desenex[5]	Undecylenate	*DesenexMax* contains terbinafine (like *Lamisil AT*). *Desenex AF Prescription Strength* contains miconazole. *Desenex Antifungal Powder, Liquid Spray,* and *Spray Powder* contain miconazole. *Desenex Foot and Sneaker Deodorant* contains aluminum chlorohydrex and silica.

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Some Selected Nonprescription Product Lines	**Expected Primary Ingredient**	**Actual Primary Ingredients**
Dramamine[5]	Dimenhydrinate	*Dramamine Less Drowsy Formula* contains meclizine instead of dimenhydrinate.
Dulcolax[5,6]	Bisacodyl	*Dulcolax Milk of Magnesia & Antacid* contains magnesium hydroxide. *Dulcolax Stool Softener Liquid Gels* has docusate sodium as the only ingredient.
Excedrin[5]	Aspirin	*Excedrin PM* contains acetaminophen instead of aspirin, along with diphenhydramine. *Excedrin Quicktabs* and *Tension Headache* products contain acetaminophen with caffeine.
Lotrimin AF[5]	Clotrimazole	*Lotrimin AF* powder and sprays contain miconazole. *Lotrimin Ultra* contains butenafine.
Maalox[5]	Aluminum and magnesium hydroxides antacid	*Maalox Max* and *Gas-X Maalox Extra Strength* contain calcium carbonate and simethicone. *Quick Dissolve Maalox Chewable Tablets* contain calcium carbonate. *Maalox Total Stomach Relief* contains bismuth subsalicylate.
Midol[5]	Acetaminophen and pamabrom	*Midol Cramps & Body Aches* contains ibuprofen. *Midol Menstrual Complete* has acetaminophen, caffeine, and pyrilamine.
Monistat[5]	Miconazole	*Monistat 1* vaginal ointment contains tioconazole.
Mylanta[5]	Aluminum and magnesium hydroxides antacid with simethicone	*Mylanta AR* contains famotidine, *Mylanta Gas* contains simethicone, and *Children's Mylanta Chewable* contain calcium carbonate. *Mylanta Ultra Tabs, Mylanta Gelcaps,* and also *Mylanta Supreme* contain calcium carbonate and magnesium hydroxide.
Pepto-Bismol[5]	Bismuth subsalicylate	*Pepto Diarrhea Control* contains loperamide.
Sinarest, Sine-Off, Sinutab[5]	Decongestant and antihistamine	These sinus product lines all have non-drowsy formulations that do not contain an antihistamine.
Tavist[5]	Clemastine	*Tavist Sinus* contains acetaminophen and pseudoephedrine, but no antihistamine.
Unisom[5]	Doxylamine	*Unisom SleepGels* contain diphenhydramine.

Some Selected Nonprescription Product Lines	**Expected Primary Ingredient**	**Actual Primary Ingredients**
Examples of Canadian Brand Name Extensions		
Benylin[8]	Dextromethorphan and guaifenesin	*Benylin First Defense Herbal Syrup* and *First Defense Cough Lozenges* contain echinacea and menthol. *Benylin Energy Boosting Herbal Syrup* and *Lozenges* have Siberian ginseng. *Benylin DM Freezer Pops, Benylin for Children DM 12 Hour Syrup, Benylin DM Syrup, Benylin DM For Children Syrup,* and *Benylin DM 12 Hour Syrup* contain only dextromethorphan. *Benylin DM-D For Children Syrup* and *Benylin DM-D Syrup* contain dextromethorphan plus pseudoephedrine. *Benylin E Extra Strength Syrup* contains guaifenesin.
Contac[8]	Acetaminophen, diphenhydramine, and pseudoephedrine	*Non Drowsy Regular Strength Contac Cold 12 Hour* contains only pseudoephedrine. *Non Drowsy Regular Strength Contac Cold Chest Congestion* has both pseudoephedrine plus guaifenesin. *Contac Cold and Sore Throat Caplets* and *Non Drowsy Super Strength Contac Complete* both contain acetaminophen, dextromethorphan, and pseudoephedrine. *Non Drowsy Extra Strength Contac Cold Sore Throat* contains acetaminophen and pseudoephedrine.
Midol[8]	Acetaminophen and pamabrom	*Midol Regular* and *Extra Strength Midol* contain aspirin and caffeine. *Midol Extra Strength Gelcaps* and *Midol Extra Strength Menstrual* have acetaminophen, caffeine, and pyrilamine.
Prodiem[8]	Calcium polycarbophil	*Prodiem Overnight Relief Therapy* contains sennosides. *Prodiem Bulk Fibre Therapy Powder* and also the *Sugar Free* contain methylcellulose. *Prodiem Plus* and *Prodiem Plain* have plantago seed as their sole ingredient.
Unisom[8]	Doxylamine	*Unisom SleepGels* and *Nighttime Sleep Aid Tablets* contain diphenhydramine. *Unisom Natural Source* contains valerian.

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Dulcolax Brand Name Extensions and *Kaopectate* Labeling Revisions

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Background

Both *Dulcolax* and *Kaopectate* products have changed, creating the potential for medication mix-ups.

The expected ingredient in *Dulcolax* has always been the laxative bisacodyl. Last year, two new products became available from Boehringer: *Dulcolax Stool Softener Liquid Gels* containing docusate sodium and *Dulcolax Milk of Magnesia & Antacid* containing magnesium hydroxide.[1]

These brand name extensions add to the list of already confusing products.

Kaopectate's formulation has changed several times. The original formula contained kaolin and pectin which was re-formulated to contain only attapulgite. In 2003 all *Kaopectate* products were changed to bismuth subsalicylate.

Consumers looking to buy *Kaopectate* may find all three formulations on shelves.

Brand Name Confusion

The practice of reusing brand names for products with different ingredients is not a new one in the OTC industry. Examples include *Tavist Sinus,* which contains no antihistamine, Bayer products with no aspirin, and *Dramamine Less Drowsy Formula,* which contains meclizine instead of dimenhydrinate. The use of a well-known brand name for a new product provides instant name recognition, but the practice also creates confusion for the consumer and could potentially be dangerous or lead to an incorrect therapeutic outcome.[2]

Dulcolax confusion has already been reported. A patient scheduled to have a colonoscopy received written directions from his physician to take two "*Dulcolax"* each day for two days prior to the procedure. The patient selected *Dulcolax Stool Softener* from the pharmacy shelf instead of the *Dulcolax Laxative* product.[3]

There are other situations where brand name extensions could cause problems. Patients with high blood pressure seeking an antihistamine OTC product (e.g., *Allerest*) could mistakenly purchase *Allerest No-Drowsiness*, which contains the decongestant pseudoephedrine. Other patients might use a product without receiving the benefits they were expecting. *Maalox Total Stomach Relief* contains bismuth subsalicylate, but no antacid. This could also present problems for a salicylate sensitive patient.

As a result of a loophole in the Code of Federal Regulations, pharmaceutical companies are allowed to market new over-the-counter products without approval of the product name by the Food and Drug Administration.[3]

Kaopectate Changes

With the potential for different *Kaopectate* formulations still being available, the unwary consumer may think that they have the old familiar product, when they don't.

This is a problem especially for those sensitive to salicylates or aspirin, children, and those taking other drugs that commonly interact with aspirin. Furthermore, darkening of the tongue or stools due to the new bismuth formulation may create patient distress.

These re-formulation concerns are not the only problem.

As of April 19, 2004 the FDA final monograph on antidiarrheal products containing bismuth subsalicylate states labeling only for adults and children 12 and over. Salicylates are not recommended for children because of the risk of Reye's syndrome. This is especially true for both children and teens during episodes of fever-causing illness such as chicken pox or flu. No product recalls for labeling change were mandated. The new *Kaopectate* bismuth formula will potentially be on shelves with two different labels and instructions.[9]

Commentary

Regulations should be changed to allow the FDA greater oversight in OTC product naming and relabeling by manufacturers. Brand name extensions should not be allowed unless the new product contains the expected primary ingredient of the original brand. Significant label changes, especially in pediatric dosing, should warrant

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recall. Furthermore, labels should provide clear differentiation of the products, warnings, directions, and indications.

Physicians, pharmacists, and healthcare practitioners should provide clear information for patients and consumers with written and verbal instructions to assure patient understanding. Pharmacists can help by discussing product selection with their customers. Selective purchase of brand name extension products is to be encouraged to prevent confusion. Separating products by intended use or therapeutic category on shelves may be another helpful technique. Removal of old formulations and products with revised labels can greatly help prevent safety problems.

Encourage reporting of potential product problems or actual occurrences. To report product problems, call the FDA MEDWATCH program at 1-800-FDA-1088. The MEDWATCH program is also available on-line at www.fda.gov/medwatch. Or report to the USP Medication Errors Reporting Program in cooperation with the Institute for Safe Medication Practices at 1-800-23-ERROR or at www.usp.org/patientSafety/reporting/mer.html. You can also contact the Institute for Safe Medication Practices (ISMP) by calling 215-947-7797 or reporting on-line at www.ismp.org/Pages/communications.asp.

There are many more products of this nature on the market. A list of some confusing brand name extensions can be found at the beginning of this document.

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References

1. Product information for *Dulcolax Stool Softener Liquid Gels* and *Dulcolax Milk of Magnesia & Antacid.* Personal communication Boehringer Ingelheim. Ridgefield, CT 06877. May 14,2004.
2. The United States Pharmacopeial Convention. OTC names: An invitation to err? *Quality Review* 1996;No. 54.
3. Institute for Safe Medication Practices. *Medication Safety Alert 2004*;9:1-2.
4. Product information for *Alka-Seltzer.* Bayer Consumer Care Division. Morristown, NJ 07962. http//www.alka-seltzer.com. (Accessed May 13, 2004).
5. OTC product information. *DrugStore.com*. http//www.drugstore.com. (Accessed May 13, 2004).
6. Product information for *Dulcolax.* Boehringer Ingelheim. Ridgefield, CT 06877 http//www.dulcolaxusa.com. (Accessed May 13, 2004).
7. Product information for *Kaopectate.* Pfizer Inc. NY, NY 10017. http//www.acidrelief.com. (Accessed May 13, 2004).
8. Drug Product Database. Health Canada. http//www.hc-sc.gc.ca/hpb/drugs-dpd/. (Accessed May 13, 2004).
9. Federal Register, Rules and Regulations; *Antidiarrheal drug products for over-the-counter human use; final monograph*. April 17, 2003;68:18869-82.

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