

Updates for *Essentials of Nonprescription Medications and Devices* June 2013

Chapter	Page	Heading/subheading	Update information December 2013
2	29	Genetic testing	<p>Several manufacturers who market genetic testing devices began to promote their products as tests that could diagnose a person's risk for certain health conditions. The FDA never approved these products for this purpose and the manufacturers received warning letters from the FDA. 23andMe, one of these companies, stopped marketing its product for this purpose.</p> <p>Reference: Genetic Test Maker 23andMe Stops Marketing After FDA Warning. <i>Medscape</i> Dec. 03, 2013.</p>
3	62	Antidiarrheals/Loperamide	New Product: Vapriano A-D contains loperamide 2 mg.
4	73	Allergies/ Glucocorticoids (New Category)	<p>Triamcinolone acetonide. This is a new Rx-to-OTC switch was approved by the FDA for the temporary relief of nasal allergy symptoms. The body's response to an allergen results in the activation of the immune system with the release of histamine, leukotriene, and other inflammatory mediators.</p> <p>Glucocorticoids suppress the immune response, thus preventing the symptoms associated with allergic reactions. The product is used as a nasal spray once a day, providing relief from nasal congestion, runny nose, watery secretions, itching and sneezing. It is most effective when used prior to exposure of the allergen. This product, Nasacort Allergy 24HR, will not be available until Spring 2014.</p> <p>Reference: FDA Approves over-the-counter Nasacort Allergy 24HR to treat hay fever and nasal allergies. Available at: http://fda.gov/drugs/newsevents/ucm/370973.htm.</p>
4	85	Asthma/ Epinephrine	The December 2012 Updates discussed the availability of racemic epinephrine in the product, Asthmanefrin, as a bronchodilator for treating asthma. The manufacturer's advertising claimed the product was a replacement for the discontinued product of Primatene Mist which contained epinephrine.

			<p>Proper use of the product required the use of a device for oral inhaler, EZ Breathe Atomizer. The FDA recalled this device in June 3013 because of a defect.</p> <p>In September 2013 the FDA notified the company that although racemic epinephrine was approved in the OTC monograph, it was not identical to epinephrine and the manufacturer could not claim that it was a substitute for Primatine Mist.</p> <p>The FDA also notified the company that there were reports of serious adverse effects including increases in blood pressure, chest pain, nausea and vomiting. The FDA plans to review the safety and use of this product as an OTC drug.</p> <p>The product has not been available since Fall 2013.</p> <p>Reference: Safety Concerns with Asthmanefrin and the EZ Breathe Atomizer. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm370483. Accessed October 29, 2013.</p>
6	120	Emergency Contraception/Levonorgestrol	<p>HRA Pharma, the French manufacturer of Norlevo, an emergency contraceptive identical to Plan B, announced a dramatic change in the labeling of this product in November 2013. New labeling states that the product is not effective in women weighing more than 176 pounds, and is less effective in women between 165 to 176 pounds. Original research by Glasier <i>et al.</i> that appeared in <i>Contraception</i> in 2011 led the manufacturer to conduct further studies into the effectiveness of Norlevo. The FDA plans further review of Plan B in 2014.</p> <p>Reference: Glasier A, <i>et al.</i> Can we identify women at risk of pregnancy despite using emergency contraception? Data from randomized trials of ulipristal acetate and levonorgestrol. <i>Contraception</i> 2011;84(4);1363-7.</p>
8	178	First Aid Topical Antiseptics	<p>The FDA announced that it would review antibacterial (antimicrobial or antiseptic) soap products in 2014. Among the concerns expressed by the FDA is the possibility of increasing the problem of bacterial resistance due to overuse and/or improper use of</p>

		<p>OTC antimicrobial or antiseptic soaps. These products are intended only to prevent bacterial infections, not to treat infections. The FDA recommends regular soaps rather than antibacterial soaps to cleanse skin.</p> <p>One of the antibacterials of concern is triclosan. Triclosan has the ability to alter certain hormones in the body. Triclosan also appears in some pesticides, and the Environmental Protection Agency (EPA) regulates its use. The FDA and EPA will jointly review the safety, use and regulation of triclosan in 2014.</p> <p>Reference: FDA Taking Closer Look at “Antibacterial” Soap. Available at: http://www.fda.gov/For Consumers/ConsumerUpdates/ucm378393. Accessed December 16, 2013.</p>
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