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

Chapter	Page	Heading/subheading	Update information June 2013
6	115	Urinary tract incontinence	Overactive bladder patch for women: The FDA approved the first OTC product for urinary incontinence on January 25, 2013. Merck, the manufacturer, plans to market the product, Oxytrol for Women, in the fall of 2013. This product is a RX to OTC switch. The sudden urge to urinate and leakage of urine occurs frequently in the older population, primarily those over 65 years of age. The most frequent cause of these symptoms in women is involuntary contraction of the detrusor muscle of the urinary bladder. This muscle is innervated by cholinergic nerve fibers. Oxybutynin, an anticholinergic drug, is a prescription drug that has been used for many years to treat this condition. The FDA has approved a patch formulation containing 3.9 mg of oxybutynin for women 18 years of age or older for OTC use. Oral forms of the drug for use by women and men are restricted to prescription use. The patch is to be applied to dry skin every 4 days. Adverse effects include mild irritation of the skin at the site of application, dry mouth and constipation. If there is no improvement of symptoms, the individual should consult a doctor. The FDA also requires that educational information about incontinence other methods to control it be included with the product. Reference: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm336815.htm. Accessed February 17, 2013.
6	120	Emergency contraception	The FDA has approved the use of levonorgestrel in the single tablet dose of 1.5 mg for women of any age. The previous labeling was restricted to women 18 years of age or older. This action was taken by FDA after a federal judge ruled on a citizen's appeal for the age elimination. Plan B has FDA approval for the single dose of 1.5 mg levonorgesterol. A generic form of the drug, Next Choice, contains 2 tablets of 0.75 mg levonorgesterol. It is still unclear as to whether or not the labeling change for age use will apply to the generic formulation.

			Reference: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm350230.htm. Accessed May 5, 2013.
9	200	Warnings and Precautions	Smoking continues to be one of the greatest risks for lung diseases including emphysema, chronic obstructive lung disease and lung cancer. Smoking also increases the risk for heart disease, stroke and other cancers. The addictive nature of nicotine content in tobacco products causes many individuals to fail at their attempt to stop smoking or to relapse and resume smoking. New prescription drugs have been developed to assist patients who wish to cease smoking and newer methods to use OTC smoking cessation products have also been tried. The success of newer methods for using OTC nicotine replacement products has led FDA to revise the labeling for these products. The most important change has been elimination of the warning, "Do not use this product if you continue to smoke, chew tobacco, use snuff or use other smoking cessation products." The individual is advised to pick a date to stop smoking and begin using the nicotine replacement product even if the individual is still smoking. New labeling will include a statement to allow continued use of the nicotine replacement product beyond the recommended dosing schedule if the individual believes that it is necessary. The individual is directed to consult the health care professional in this situation. Reference: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm345087.htm?source=govdelivery. Accessed April 4, 2013.