Revised section

Chapter	Page	Heading/subheading	Update information November 2011
3	41	Gas and bloating/alternative therapy/alpha-galactosidease	New product: Beano Meltaways Directions: melt on tongue before the first bite of food; 1 meltaway tablet is equivalent to 2 oral Beano tablets.
	43	Nausea and vomiting/antiemetics for motion sickness	New product: Zentrip: 25 mg meclizine in each oral disintegrating strip; limit of 2 strips per day. Directions: use 1 hour before event that causes motion sickness; do not use in children less than 12 years old.
	49	Pinworms/pryantel pamoate	New product: Pronto Plus Pinworm.
	63	Probiotics	New products: Colon Health Probiotic: contains Lactobacillus gasseri KS-13, Bifidobacterium bifidum G9-1, and Bifidobacterium longum MM-2. New Product: Colon Health Probiotic + fiber: contains the same organisms plus 3 grams of inulin (fiber) per dose.
4	77	Allergies/combination allergy drug therapy/ decongestants and analgesic products	New product: Robitussin: Peak Cold Nasal Relief.
	77	Common cold/antitussives	There is concern about the abuse of products containing dextromethorphan, especially by adolescents. An FDA Advisory Panel reviewed the OTC status of this drug, concluding that further study was needed before any restriction for OTC use would be adopted.

	79	Common cold/central acting antitussive	Name change: Robitussin Cough Gels now Robitussin: Lingering Colds Long Acting Cough Gels.
	80	Common cold/combination cold products	Name change: Robitussin DM now Robitussin Peak Cold: Cough + Chest Congestion DM.
	84	Asthma/epinephrine	Epinephrine oral inhalers containing chlorofluorocarbons will not be available after December 31, 2011. Primatene Mist is the product affected. Patients should see their doctor for appropriate treatment. (Reference: http://www.fda.gov/forConsumers/ConsumerUpdates/ucm247196.htm. Accessed: September 23, 2011.)
5	90	Oral analgesics/ acetaminophen	An Advisory Panel of the FDA reviewed medication errors associated with the use of acetaminophen and made several recommendations to help decrease the risk of errors. One recommendation was to standardize the concentration of all liquid acetaminophen products and to adopt a uniform measuring device for pediatric dosing. The Consumer Healthcare Products Association (CHPA), a national trade organization of OTC drug manufacturers, announced adoption of this recommendation by all of its members in May 2011. All future manufacture of liquid acetaminophen products by CHPA members will contain 160 mg/5 mL and an age appropriate dosing device for pediatric patients beginning in mid 2011. This action may create confusion because the current supplies of acetaminophen infant drops containing 80 mg per 0.8 mL are still available in retail outlets, including pharmacies. There has been no FDA recall of the infant drop formulations and they may continue to be sold. Also, many caregivers may have infant drops in the home and will probably continue to use them until the container is empty. The recommended dose of acetaminophen remains the same for children, 10 to 15 mg per kg of body weight. A person purchasing

			newly manufactured acetaminophen will find different dosing directions because of the change in concentration and pharmacists should advise purchasers of this change. When a pharmacist is asked about a pediatric dose of acetaminophen, they must first ask the caregiver to read the exact label of the product in order to avoid giving incorrect dosing information, since old and new product formulations are both available. It may take 1 to 2 years before all the liquid acetaminophen products in the marketplace are replaced by the new 160 mg/5 mL formulation. Pharmacists and consumers must be aware of the fact that not all manufacturers are members of CHPA, and that this change is voluntary. Internet purchasers must also be aware of the fact that manufacturers outside of the US are not bound by this voluntary policy. Reference: http://www.chpa-info.org/pressroom/05_05_11_PedAceConv.aspx. Accessed: August 12, 2011. McNeil, the manufacturer of Tylenol products has initiated a new, voluntary program, Get Relief Responsibly, that encourages safe use of acetaminophen. McNeil estimates that 600 OTC and prescription products contain acetaminophen. McNeil plans to change its recommendation from the maximum daily dose of 4,000 mg a day of its Extra Strength Tylenol products to 3,000 mg a day in the Fall of 2011 in an effort to reduce over use of acetaminophen. Reference: http://www.tylenol.com/page2.jhtml?id=tylenol/news/newdosing.inc. Accessed: November 14, 2011.
6	116	Products for men/dietary supplement for benign prostate hyperplasia (BPH)	The most recent clinical trial to evaluate increasing doses of saw palmetto extract to relieve symptoms of BPH failed to demonstrate any benefit compared with placebo. Doses examined were 320 mg/d

			(the current recommended dose), 640 mg/d, and 940 mg/d. Reference: Barry MJ, Meleth S, Lee JY *et al. JAMA* 2011;306:1344−1351.
8	175	Sunscreens/monograph sunscreens	The Final Rule for labeling of sunscreens includes the following new indication for use for all products having a SPF >15: If used as directed with other sun protection measures this product will decrease the risk of skin cancer and early aging of the skin caused by sun exposure. Additional directions for proper use include: apply liberally 15 minutes before sun exposure; water resistant (reappliction after 40 minutes in the water) and very water resistant (reapplication after 80 minutes in the water) should be reapplied every 2 hours if not in the water. Use of the terms sunblock, waterproof or sweat proof is not permitted in product labeling. Reference: Labeling and effectiveness testing; Sunscreen drug products for over-the-counter human use. *Fed Regist* 2011; 76:35620−35665.
9	197	Weight loss products	The search for safe products that promote weight loss has included the dietary supplement Hoodia gordonii, specifically 2 major steroid glycosides referred to as *HG*PE. A small (49 healthy overweight women), short (15 day) randomized, double-blinded, placebo controlled clinical trial did not demonstrate any significant weight loss or decrease in energy intake. Adverse effects of Hoodia compared to placebo including nausea and vomiting, increased blood pressure, heart rate, and pulse, and increased levels of bilirubin and alkaline phosphatase. Reference: Blom WAM, Abrahamse SL, Bradford R, *et al.* Effects of 15-d repeated consumption of Hoodia gordonii purified extract on safety, ad libitum energy intake, and body weight in healthy, overweight women: a randomized controlled trial. *Am J Clin Nutr* 2011;94:1171−1181.

			Many dietary supplement weight loss products do not contain the label ingredients and/or may be contaminated with prescription drugs. The FDA continues to issue safety warnings about weight loss products, including Hoodia supplements. Reference: Beware of fraudulent weight-loss dietary supplements. Available at: http://www.fda.gov/ForConsumers/ConsumerUpdates.ucm246742.htm. Accessed: July 14, 2011.