**FDA Approves First Generic Versions of Ambien®**

On April 23, 2007, the Food and Drug Administration (FDA) approved the first generic versions of Ambien® (zolpidem tartrate) immediate-release tablets. Zolpidem tartrate is a sedative-hypnotic drug indicated for the short-term treatment of insomnia. Generic versions of zolpidem tartrate immediate-release have been approved for thirteen manufacturers for tablet formulations in five and ten milligram strengths. In March, 2007, the FDA requested that all manufacturers of sedative-hypnotics strengthen the labeling for their products to include stronger language related to their potential risks. Risks include severe allergic reactions and complex sleep-related behaviors, including sleep driving. Sleep driving is defined as driving while not fully awake with no memory of the event. This labeling, related to potential risks, will also be included in labeling of generic versions of the drug. The patent for zolpidem tartrate, held by Sanofi-Aventis (formerly Sanofi-Synthelabo) expired on April 21, 2007. Generic versions of Ambien® are expected to be available for dispensing almost immediately.

**Updated Recommended Treatment Regimens for Gonococcal Infections in the United States**

As a result of ongoing data from the Centers for Disease Control and Prevention’s (CDC’s) Gonococcal Isolate Surveillance Project (GISP), including preliminary findings from 2006, that demonstrate fluoroquinolone-resistant gonorrhea is continuing to spread and is now widespread in the United States, fluoroquinolones are no longer the recommended antibiotic treatment for gonorrhea in the United States. Officials at the CDC are now urging physicians to treat cases of gonorrhea with the cephalosporin class of antibiotics. A single dose of intramuscular (IM) ceftriaxone or oral cefixime (available as powder for oral suspension) is recommended for treatment of uncomplicated gonococcal infections of the cervix, urethra and rectum; a single dose of IM ceftriaxone is recommended for treatment of uncomplicated gonococcal infections of the pharynx; and IM or intravenous (IV) ceftriaxone are recommended for treatment of disseminated gonococcal infection (DGI). A cephalosporin-based intravenous regimen is recommended for the initial treatment of DGI. This is particularly important when gonorrhea is detected at mucosal sites by nonculture tests. Treatment of DGI should be continued with IV or IM, preferably IV, cephalosporins, for 24-48 hours after clinical improvement, then therapy may be switched to oral cefixime or cefpodoxime to complete at least one week of antimicrobial therapy. With no new antibiotics in the pipeline to treat gonorrhea, the United States is in a dangerous situation, having only one class of drugs, to treat the second most commonly reported infectious disease, behind chlamydia, another sexually transmitted disease. The United States has an estimated 700,000 new cases of gonorrhea a year, occurring among sexually active people of both genders at all ages. If antimicrobial susceptibility can be documented by culture, fluoroquinolones may be an alternative treatment option for gonorrhea.

**Drug Information Highlights**

- **Tigan® (and other various marketed names) (trimethobenzamide):** The FDA notified healthcare professionals and consumers that companies must stop manufacturing and distributing unapproved suppository products containing trimethobenzamide, a medication used to treat nausea and vomiting in adults and children. This is due to a lack of evidence of effectiveness of this dosage form. This does not affect oral capsule and injectable trimethobenzamide products.

- **Grifulvin V® (griseofulvin oral suspension, microsize 125 mg/5mL) and griseofulvin oral suspension (Patriot Pharmaceuticals, L.L.C.):** Liquid formulation distributed in glass bottles recalled based on two reports of glass fragments found in bottles of this medication.

- **Zanaflex® (tizanidine):** Changes to the contraindications and warnings sections of product labeling reflect findings of pharmacokinetic studies in which tizanidine was co-administered with either fluvoxamine or ciprofloxacin, both CYP1A2 inhibitors, and the serum concentration of tizanidine was significantly increased potentiating its hypotensive and sedative effects. Co-administration of other CYP1A2 inhibitors including zileuton, other fluoroquinolones, antiarrhythmics, cimetidine, famotidine, oral contraceptives, acyclovir and ticlopidine should also be avoided even though there are no clinical studies evaluating their co-administration with tizanidine.
Avastin® (bevacizumab): Although Avastin® is not approved for treatment of small cell lung cancer (SCLC), recent clinical studies of its use in combination with chemotherapy and radiation in patients with this condition have revealed confirmed cases of tracheoesophageal (TE) fistula formation. Current prescribing information includes a description of gastrointestinal tract fistula formation in patients treated with Avastin® for colorectal and other cancer.