NEW DRUGS

Generic Approvals

Generic MetroGel for Vaginosis

The Food and Drug Administration (FDA) has approved the first generic version of metronidazole vaginal gel (MetroGel, QLT USA), a treatment for bacterial vaginosis. This infection is characterized by vaginal discharge, and it results from an overgrowth of bacteria in the vagina.

(Source: FDA, November 1, 2006.)

Generic Ditropan For Overactive Bladder

Final approval has been granted for Mylan’s Abbreviated New Drug Applications (ANDAs) for oxybutynin chloride extended-release 5-mg and 10-mg tablets. The product is the generic version of Alza Corporation’s Ditropan XL.

As a genitourinary antispasmodic agent, the tablets are indicated for overactive bladder.

(Source: Mylan Laboratories, November 10, 2006.)

Generic Mobic for Arthritis

Taro Pharmaceutical Industries has received approval for its ANDA of meloxicam tablets 7.5 mg and 15 mg for the relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis. This Taro product is bioequivalent to Boehringer Ingelheim’s Mobic Tablets.

(Source: Taro, November 8, 2006.)

Generic Pravachol For Lowering Lipids

Barr Pharmaceuticals, Inc. and its subsidiary Pliva d.d. have announced that Pliva has received final approval from the FDA for its ANDA to manufacture and market Pravastatin tablets in dosages of 10 mg, 20 mg, and 40 mg. The tablets are the generic version of Bristol-Myers Squibb’s Pravachol tablets.

Pliva has also received tentative approval to make the 80-mg dose.

Pravastatin is indicated for the primary prevention of coronary events in patients with elevated cholesterol levels who do not have clinically evident coronary heart disease and for the secondary prevention of cardiovascular events in patients with clinically evident coronary heart disease.

(Source: Barr Pharmaceuticals, November 28, 2006.)

Generic Ondansetron Injection for Preventing Nausea

The FDA has approved generic versions of GlaxoSmithKline’s ondansetron Premixed Ondansetron is indicated for preventing chemosurgery-associated and postoperative nausea and vomiting.

The injection (Teva Pharmaceuticals) is available in single (4-mg/2 ml) and multidose (40-mg/20 ml) packages. The premixed product (32 mg/50 ml in 5% dextrose) is manufactured by Sicor Pharmaceuticals.

(Source: FDA, November 27, 2006.)

Clindamycin/Tretinoin for Acne

The FDA has approved a combination of clindamycin phosphate 1.2% and tretinoin 0.025% (Ziana, Medicis/Dow Pharmaceutical Sciences, Inc.) for the topical treatment of acne vulgaris in patients 12 years of age or older. The gel is the first approved acne product to combine an antibiotic and a retinoid.

Available by prescription in 30-g and 60-g tubes, the product has an alcohol-free, aqueous base.

Adverse events include nasopharyngitis, pharyngolaryngeal pain, dry skin, cough, and sinusitis. The gel is contraindicated in people with regional enteritis, ulcerative colitis, or a history of antibiotic-associated colitis. Exposure to sunlight, including sunlamps, should be avoided during use.

(Sources: Medicis/Dow, November 7, 2006; www.medicis.com.)

NEW INDICATIONS

Pramipexole for Restless Legs

Pramipexole dihydrochloride tablets (Mirapex, Boehringer Ingelheim) has been approved for the treatment of moderate-to-severe primary restless legs syndrome (RLS). RLS is a common neurological sensorimotor disorder. Patients typically describe an urge to move the legs, and they may experience burning, creeping, crawling, aching, tingling, or tugging sensations in the legs. Up to 10% of adults in the U.S. are affected.

Pramipexole is also approved to treat Parkinson’s disease.

(Source: Boehringer Ingelheim, 2006.)

Trastuzumab for Early-Stage Breast Cancer After Primary Therapy

The FDA has expanded the approved use of trastuzumab (Herceptin, Genentech), a biological cancer drug. In combination with other cancer drugs, trastuzumab is indicated for patients with HER2-positive breast cancer after surgery.

Herceptin is a targeted therapy against the HER2 protein on cancer cells. An excessive amount of HER2 protein causes cancer cells to grow more rapidly, and standard chemotherapy may be less effective. Approximately 25% of women with breast cancer have tumors that produce excessive HER2 protein.

In 1998, the drug was approved for the treatment of metastatic breast cancer. The new approval expands its use to women with cancer only in the breast or lymph nodes that has been surgically removed.

Studies conducted by the National Cancer Institute were ended early because of the positive results. Women who received trastuzumab combined
with chemotherapy had fewer relapses for up to three years after surgery. The estimated three-year disease-free rates were 87% in patients receiving trastuzumab and chemotherapy and 75% in those patients receiving chemotherapy alone.

The most serious side effect was heart failure. Patients must be screened for heart function before and during therapy. (Source: FDA, November 16, 2006.)

**Adalimumab May Lessen Joint Damage in Psoriatic Arthritis**

The FDA has approved an expanded indication for the human monoclonal antibody adalimumab (Humira, Abbott) that includes inhibiting structural joint damage and improving physical function in patients with psoriatic arthritis (PsA). This indication is in addition to the approval for PsA that was granted in October 2005.

This product is also approved for moderate-to-severe rheumatoid arthritis and active ankylosing spondylitis.

PsA, an autoimmune disorder, combines symptoms of arthritis, including joint pain and inflammation, and those of psoriatic skin disease, such as painful, raised red lesions covered by silvery-white scales. The additional indication was based on results from an extension of the Adalimumab Effectiveness in Psoriatic Arthritis Trial (ADEPT).

(Source: Abbott, November 14, 2006.)

**NEW FORMULATION**

*Nitroglycerin Spray for Angina*

Nitroglycerin Lingual Aerosol (Nitro-Mist, Nova Del Pharma) has been approved for the acute relief of an attack or acute prophylaxis of chest pain caused by coronary artery disease.

NitroMist is Nova Del’s first approved product to use a proprietary oral spray technology. The North American commercial rights have been licensed to Par Pharmaceutical.

Severe hypotension, particularly with upright posture, may occur with even small doses of nitroglycerin. This drug should therefore be used with caution in patients who may be volume-depleted or who are already hypertensive.

(Source: Nova Del Pharma, Inc., www.novadel.com)

**DRUG NEWS**

**New Warning for Tamiflu Label**

The FDA recommends that patients who take Tamiflu (Roche) to treat influenza be closely monitored for signs of abnormal behavior. Tamiflu is indicated for patients one year of age and older with uncomplicated acute illness caused by influenza who have shown symptoms for no more than two days.

More than 100 new cases of delirium, hallucinations, and other unusual psychiatric behavior have been reported in children who were given the drug. Most of these patients were children in Japan, where Tamiflu usage is the highest in the world. The new cases of behavioral changes occurred between August 2005 and July 2006.

Health officials have been sensitive about taking any action that might dissuade people from taking Tamiflu, because the drug may be important in an outbreak of bird flu.

The drug does not prevent influenza, but it can reduce the length and severity of associated symptoms.

(Source: Associated Press, November 14, 2006.)

**NEW MEDICAL DEVICES**

*Precise Nitinol Stent/Angio-\*guard Emboli Capture Guidewire*

**Name:** Precise Nitinol Stent/Angio-\*guard Emboli Capture Guidewire  
**Manufacturer:** Cordis Endovascular, Miami, FL

Approval Date: October 19, 2006  
Use Classification: The device is used to treat blocked arteries in the neck.

Description: The Nitinol stent has high radial strength and easily withstands the pressure of the carotid artery, increasing lumen diameter with chronic outward force. The stent’s micromesh geometry and segmented design help to ensure that it conforms to the artery wall and that it maximizes lumen coverage. Arterial wall apposition is immediate and continuous because the stent has a 1-mm flare at each end.

This is the first embolic protection device to achieve a relative stroke reduction of 70% during carotid stenting. The polyurethane membrane, with its 100 pores, captures clinically relevant emboli. Eight Nitinol struts keep the symmetrical basket in contact with the arterial wall and help to ensure that debris does not escape.

Purpose: The stent and guidewire are approved to treat carotid artery disease in patients at high risk for adverse events from carotid endarterectomy, a surgical procedure in which arterial plaque is removed from the carotid artery.

Benefit: This the only carotid system to be supported by a large, randomized clinical study—Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE). The study revealed a low rate of revascularization of the target lesion (less than 1%) and a low rate of stroke, thereby demonstrating the system’s integrity and long-term durability.

Sources: www.pharmacyonesource.com; Johnson & Johnson gateway, www.jnjgateway.com

Name: Reveal G3 Rapid HIV-1 Antibody Test (Reveal G3)  
Manufacturer: MedMira, Inc., Halifax, Nova Scotia

Approval Date: October 19, 2006

continued on page 715
Use Classification: This is the third generation in the Reveal line of rapid tests for detecting the human immuno-deficiency virus (HIV). The test can be used to detect occupational exposure to the virus in hospital workers, in women in labor and delivery units, and in patients in emergency departments.

Description: In September, the Centers for Disease Control and Prevention (CDC) recommended routine HIV testing for everyone 13 to 64 years of age. It is estimated that more than 250,000 HIV-positive people in the U.S. are unaware of their status. The recent CDC recommendations also include enhanced screening of pregnant women to decrease the rate of mother-to-child transmission.

Purpose: The test is used for quick HIV detection.

Benefit: Results are delivered in less than three minutes. The InstantGold Cap replaces the colorimetric detection agent used to visualize results on the test cartridge. This advance eliminates the need for reconstituting and refrigerating the detection agent, thereby improving the product’s overall ease of use.

Source: www.pharmacyonesource.com; www.medmira.com

Name: Near Infrared Spectroscopy System

Manufacturer: InfraReDx, Burlington, MA

Approval Date: October 19, 2006

Use Classification: This device is used to examine the coronary arteries and to identify the chemical components of arterial plaques.

Description: This novel fiber-optic, catheter-based device is equipped with a laser light source. The chemical content of substances can be identified by shining infrared light at a target and measuring the amount of light reflected at different wavelengths.

Purpose: The catheter is designed to perform spectroscopy in the difficult conditions of motion and blood flow associated with the coronary arteries. During coronary angiography, the system can identify plaque composition; it measures light that is delivered through the blood and reflected from the artery wall.

Benefit: The rapid speed of acquiring the image freezes heart motion and permits scanning of the artery in less than two minutes. The system produces a map of the artery’s chemical composition that provides additional information to assist physicians in patient care.

Sources: www.pharmacyonesource.com; www.infraredx.com

Counterfeit Product Alert

LifeScan and the FDA have notified health care professionals and the public of counterfeit blood glucose test strips being sold in the U.S. for use with various models of the LifeScan OneTouch Blood Glucose Monitors. Diabetic patients use the monitors to measure their blood glucose levels. The counterfeit test strips have the potential to give incorrect values—either too high or too low. This defect can cause patients to take either too much or too little insulin and may lead to serious injury or death. No injuries have been reported to FDA to date.

The affected test strips are as follows:

• OneTouch Basic/Profile (Lot Nos. 272894A, 2619932, and 2606340)
• OneTouch Ultra (Lot Nos. 2691191 and 2691261)

The problem does not involve OneTouch FastTake, or OneTouch SureStep test strips. Consumers who have the counterfeit test strips should stop using them, replace them immediately, and contact their physician.

Source: www.fda.gov/bbs/topics/NEWS/2006/NEW01490.html