NEW DRUGS

Micafungin for Candidiasis

Micafungin sodium for injection (Mycamine®, Fujisawa Healthcare) has been approved by the U.S. Food and Drug Administration (FDA) as an antifungal product for preventing Candida infections in patients undergoing hematopoietic stem-cell transplantation and for treating esophageal candidiasis. According to one study, invasive candidiasis kills 10% to 40% of infected immunocompromised patients. Its discontinuation rate was similar to that for fluconazole.

Micafungin is a member of a new class of antifungal agents, the echinocandins, which inhibit cell wall synthesis. In patients receiving micafungin, isolated cases of serious hypersensitivity reactions along with significant hemolytic anemia were reported. Injection-site reactions, including phlebitis and thrombophlebitis, occurred with doses of 50 to 150 mg/day.

(Source: Fujisawa, March 16, 2005.)

Generic Dantrium® Approved

The FDA has granted final approval to Impax’s Abbreviated New Drug Application for a generic version of Procter & Gamble’s dantrolene sodium (Dantrium®) 25-, 50-, and 100-mg capsules. Dantrolene is indicated for patients with spasticity in stroke, multiple sclerosis, cerebral palsy, and spinal cord injury.

(Source: Impax, March 2, 2005.)

Pramlintide for Glucose Control

Amylin Pharmaceuticals, Inc., has announced the FDA’s approval of pramlintide acetate (Symlin®) injection to be used in conjunction with insulin to treat type-1 and type-2 diabetes. This product is to be used at mealtime in diabetic patients who have been unable to achieve desired glucose control despite optimal insulin therapy. The self-administered injection causes less fluctuation of daytime glucose levels and better long-term glucose control than insulin alone. Patients used less insulin at mealtime and lost weight, compared with the insulin-alone patients.

The product is a synthetic analogue of human amylin, a hormone made in the beta cells of the pancreas. It may pose an increased risk of insulin-induced severe hypoglycemia, particularly in patients with type-1 diabetes within three hours following an injection. A boxed warning appears in the prescribing information.

(Sources: Amylin, March 16, 2005, www.symlin.com.)

Bromfenac Solution for Ocular Inflammation after Surgery

The FDA has approved the New Drug Application (NDA) for bromfenac ophthalmic solution (Xibrom™, ISTA Pharmaceuticals) 0.09% for the treatment of ocular inflammation following cataract surgery. This is a topical, twice-daily, non-steroidal anti-inflammatory (NSAID) solution. Senju has marketed this product in Japan since 2000, and ISTA acquired the U.S. marketing rights in 2002.

(Source: ISTA, March 28, 2005.)

Entecavir Gains FDA Approval

The FDA has approved entecavir (Baraclude™, Bristol-Myers Squibb) for the treatment of chronic hepatitis B infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. This oral antiviral therapy is designed to block the replication of hepatitis B virus in the body by interfering with the ability of the virus to infect cells.

(Source: Bristol-Myers Squibb, March 29, 2005.)

Approval for Generic Brethine®

The FDA has approved an Abbreviated New Drug Application (ANDA) for terbutaline sulfate tablets 2.5 mg and 5 mg (Lannett). This agent is indicated for the prevention and reversal of bronchospasm in patients 12 years of age and older with asthma and reversible bronchospasm associated with bronchitis and emphysema. It is the generic equivalent of Brethine® Tablets (Novartis and aaiPharma, Inc.)

(Source: Lannett Company, Inc., March 29, 2005.)

NEW INDICATION

Temozolomide for Glioblastoma Multiforme

The FDA has approved a new indication for temozolomide (Temodar®, Schering-Plough). Used concurrently with radiation therapy and as maintenance therapy after radiation, the product extended the lives of adult patients with newly diagnosed glioblastoma multiforme (GBM), the most common form of a usually fatal malignant brain cancer. Accelerated approval was granted in 1999 for adults with anaplastic astrocytoma, another type of brain tumor, and who had experienced relapse after chemotherapy with nitrosourea and procarbazine. Because of the clinically important outcome in the GBM study, the anaplastic astrocytoma indication is now approved under traditional procedures, and the accelerated approval requirements no longer apply.

(Source: FDA, March 16, 2005.)

DRUG NEWS

Once-Monthly Ibandronate for Osteoporosis

Roche and GlaxoSmithKline have announced the FDA’s approval of a once-monthly oral bisphosphonate, ibandronate sodium (Boniva®) 150-mg tablets, for patients with postmenopausal osteoporosis. This is the first oral therapy adminis-
Critical Methotrexate Shortage

A national shortage of injectable methotrexate, a drug used in the treatment of several childhood cancers, is alarming oncologists.

This agent has been in short supply because a manufacturing plant in Switzerland shut down last year because of quality-control problems. The plant is undergoing upgrades and may restart production in May or June.

Although methotrexate is used to treat cancer, rheumatoid arthritis, psoriasis, lupus, and Crohn’s disease, the shortage is primarily affecting children with leukemia, osteosarcoma, and non-Hodgkin’s lymphoma. These patients need extremely high doses that are available only in the injectable form. Adults with diseases other than cancer can often take lower doses orally or may use alternative therapies.

For the affected children, many cancer centers are now requiring doctors to notify them before chemotherapy is begun so that they can determine whether the available supply of methotrexate will be sufficient to complete the treatment.
Sales of Two Drugs on Hold

GlaxoSmithKline (GSK) has said that it could not predict whether federal authorities would let it resume selling two drugs that have been impounded because of manufacturing defects. It was also unclear whether the FDA would impose penalties after GSK resumes sales of the antidepressant paroxetine (Paxil® CR) and the diabetes drug rosiglitazone maleate/metformin (Avandamet®).

On March 4, federal marshals, acting on the FDA’s request, began seizing unsold U.S. shipments of the two drugs, citing manufacturing defects at a GSK plant in Cidra, Puerto Rico, that caused tablets to split or to vary in the amounts of active ingredients.

Both the FDA and the company emphasized that the damaged drugs were still safe, although not necessarily effective. The FDA did not order a recall, and pharmacies were allowed to sell their remaining inventory.

Ultimately, all undelivered lots were impounded in Cidra and at distribution centers in Puerto Rico; Knoxville, Tennessee; Zebulon, North Carolina; and elsewhere.

An FDA spokesperson declined to disclose the number of lots seized or the status of talks with GSK. In the past, according to GSK, the FDA has agreed to let other companies sell “medically necessary” drugs while paying a share of profits and correcting manufacturing problems. However, the FDA already seems to have decided that these two agents are not medically necessary. Resumption of sales may have to wait until the firm certifies that it has made all manufacturing corrections; this will likely be a lengthy process.

Device for Thoracic Aneurysms

The FDA has approved a device that helps to prevent ruptures of descending thoracic aneurysms by making a new path for blood flow. The Gore TAG Endoprosthesis System (W. L. Gore) is a minimally invasive endovascular grafting technique for treating aneurysms of the thoracic aorta, the main artery that carries blood in the body.

Descending thoracic aneurysms are usually managed either medically, with antihypertensive agents to reduce the risk of rupture, or surgically. Large aneurysms at risk of rupture can be fatal.

The device was approved on the basis of a review of two clinical studies of approximately 200 people. Aneurysm-related deaths were lower for patients who had received the endoprosthesis system than for the surgical control patients.

The FDA is requiring that Gore conduct post-approval studies.

(Sources: FDA, March 24, 2005; W. L. Gore, www.goremedical.com.)

NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: Cobas AmpliScreen™ HIV-1 and Hepatitis C Tests

Manufacturer: Roche Diagnostics, Indianapolis, IN

Approval Date: March 16, 2005

Use Classification: These tests are used to screen cadaveric organ and tissue donations to detect and prevent transmission of hepatitis C virus (HCV) and human immunodeficiency virus (HIV) infection.

Description: Blood and tissue-screening tests are based on the company’s highly sensitive polymerase chain reaction (PCR) technology, which has become the global standard for fast and reliable replication of minute amounts of genetic material to detectable levels.

Purpose: Screening for HIV and HCV infection.

Tissues from cadaveric sources such as skin, bone, and ligaments are used in approximately one million medical procedures per year. These tissues can transmit the same viral infections as blood, and the products from a single tissue donation may be transplanted into 50 to 100 patients.

Benefit: PCR techniques enable the detection of the genetic material of infectious agents directly, making it possible to detect infections earlier in the infection cycle than with immunoassays, often before the donor shows any disease symptoms. Currently, enzyme immunoassays, which detect antibodies to the target virus, are used to test most tissue donors. Nucleic acid tests, such as the Cobas tests, can reduce the “window period” of detection for HIV-1 from 22 days to between 13 and 15 days and for HCV from 82 days to between 22 and 32 days. This shortening of the window period (the “window of opportunity” for a donation to escape detection) enables laboratories to ensure the safety of the tissues.
Sources: www.pharmacyonesource.com; www.roche.com

Name: Nucleus® Freedom™ Cochlear Implant System
Approval Date: March 14, 2005
Manufacturer: Cochlear Americas, Denver, CO

Use Classification: The implant mimics functions of the human ear and causes minimal disruption to a patient’s lifestyle.

Description: The implant enables electrodes to be placed close to the hearing nerve for targeted stimulation and increased power efficiency. Minimal pressure is applied on the cochlear structures. The electrode array is designed to protect cochlear structures during surgery, which is essential in preserving residual hearing. This implant system has a water-resistant speech processor.

Purpose: Enhancement of hearing.

Benefit: The device offers a combination of three unique technologies designed to enhance hearing in everyday listening situations. A two-microphone system can soften distracting background sounds to enhance focused listening in crowds. The ADRO™ automatically adjusts sound levels to deliver a balance of clarity and comfort and is ideal for listening to music and for hearing in dynamic environments. The Whisper™ enhances softer sounds so that patients can understand them more clearly.

One set of batteries lasts for up to five days instead of only a few hours, as well as with other systems.

Sources: www.pharmacyonesource.com; www.cochlearamericas.com

Name: Lapex-2000 Low-Level Laser
Supplier: Meridian Medical, Inc., Vancouver, BC
Approval Date: March 14, 2005
Use Classification: This laser is indicated for alleviating pain. Low-level lasers have been effective for treating rheumatoid arthritis; immune system disorders; sports injuries; inflammation; anginapectoris; cerebral infarction; fibroid tissue disorders; and functional disorders in muscles, tendons, and joints. It also increases and improves the blood supply.

Description: A laser light is delivered to various areas of the body without damaging the skin tissue. The light source is placed in contact with the skin, allowing the photon energy to penetrate tissue. The body then converts the photon energy into biochemical energy by interacting with cellular structures, resulting in the restoration of normal cell function and enhancement of the body’s natural healing process. The Lapex-2000 is digitally controlled with a liquid crystal diode (LCD) screen and is easy to operate.

Purpose: Treatment of carpal tunnel syndrome.

Benefits: The product has the potential to reduce the need for medication and surgery while helping patients with carpal tunnel syndrome become more active and experience less pain. Pain-management specialists (e.g., physiotherapists, sports medicine professionals) who use the device might be able to improve quality of life for their patients.

Sources: www.pharmacyonesource.com; www.meridianmedical.ca

Name: Erchonia Neira 4L™ Low-Level Laser
Manufacturer: Erchonia Medical, Inc., Mesa, AZ
Approval Date: February 14, 2005
Use Classification: This device is approved for liposuction. Low-level laser therapy is commonly used to treat acute and chronic pain and produces few negative side effects.

Description: This laser addresses the negative consequences of liposuction. It produces a low-level (cold) output that has no thermal effect on the body’s tissue. Instead, the laser serves to stimulate biological function in a positive way.

Purpose: Reduction of pain and recovery time after liposuction.

Benefit: This approval represents a significant breakthrough by giving surgeons a proven, safe method for reducing postoperative pain and recovery time. Patients who are pre-treated with this laser should experience less postoperative pain. They can expect to go back to everyday life more quickly than without the laser. When treatment is administered just before surgery, the non-invasive laser facilitates the removal of fatty tissue, thus reducing trauma during the procedure. Liposuction is quicker and less painful than with other methods.

Sources: www.pharmacyonesource.com; www.erchonia.com

Recalled Device
Item: LIFEPAK® 500 Automated External Defibrillator
Recalling Firm: Medtronic, Inc.
Date: March 1, 2005
Reason for Recall: Medtronic, Inc., and the FDA have advised health care professionals of a class 1 recall of certain automated external defibrillators (AEDs). The AED may continue to display a “connect electrodes” message and may not analyze the patient’s heart rhythm even when the electrodes are properly connected. Failure to analyze the heart rhythm inhibits defibrillation if it is needed.

This action affects 1,924 of these first-generation AEDs that were manufactured in 1997, or approximately 1% of the LIFEPAK® 500 AEDs in use worldwide. The company was expected to update or upgrade customer devices at no charge by March 31, 2005.

Source: www.fda.gov/medwatch/safety/2005