

## **FDA AGENCY REPORT – MARCH 2010**

Here is a summary of recent product safety, product approvals, announcements and resources to keep you informed about FDA issues. A brief summary of each issue and a web link to detailed information on the FDA website is included.

### **PRODUCT SAFETY:**

#### **[Ongoing Safety Review of Stalevo and possible development of Prostate Cancer](#)**

(Mar. 31)

The FDA is evaluating clinical trial data that may suggest that patients taking Stalevo, a Parkinson's disease medication, may be at an increased risk for developing prostate cancer. In this trial, patients taking Stalevo were compared to those taking carbidopa and levodopa (sold as Sinemet), a combination medication also used to treat Parkinson's disease.

#### **[Components of Extraneous Virus Detected in Rotarix Vaccine; No Known Safety Risk](#)**

(Mar. 22)

FDA is recommending that healthcare practitioners temporarily suspend use of the Rotarix vaccine for rotavirus immunization in the United States while the agency learns more about components of an extraneous virus detected in the vaccine. There is no evidence at this time that this finding poses a safety risk.

#### **[FDA Warns about Increased Risk of Muscle Injury with Zocor](#)** (Mar. 19)

The FDA warned patients and healthcare providers about the potential for increased risk of muscle injury from the cholesterol-lowering medication Zocor (simvastatin) 80 mg. Although muscle injury (called myopathy) is a known side effect with all statins, today's warning highlights the greater risk of developing muscle injury, including rhabdomyolysis, for patients when they are prescribed and use higher

#### **[FDA Orders 2 Companies to Stop Marketing Unapproved Nitroglycerin Tablets](#)**

(Mar. 16)

The FDA ordered Glenmark Generics of Mahwah, N.J., and Konec Inc. of Tucson, Ariz., to stop marketing unapproved nitroglycerin tablets. The tablets are placed under the tongue to relieve chest pain or to stop a heart attack and are marketed in 0.3 mg, 0.4 mg, and 0.6 mg dosages. The FDA does not anticipate a supply problem for these products. Pfizer Inc. markets FDA-approved sublingual nitroglycerin tablets in the same strengths and is able to supply the market with approved products.

#### **[FDA Announces New Boxed Warning on Plavix](#)** (Mar. 12)

The FDA added a boxed warning to the anti-blood clotting drug Plavix (clopidogrel), alerting patients and health care professionals that the drug can be less effective in people who cannot metabolize the drug to convert it to its active form.

[FDA Approves Name Change for Heartburn Drug Kapidex](#) (Mar. 4)

Change to Dexilant is part of FDA effort to prevent medication errors - The FDA has approved a name change for the heartburn drug Kapidex (dexlansoprazole) to avoid confusion with two other medications – Casodex and Kadian. Effective in late April 2010, Takeda Pharmaceuticals North America Inc. will market Kapidex under the new name Dexilant. Since Kapidex was approved in January 2009, there have been reports of dispensing errors because of confusion with the drugs Casodex (bicalutamide) and Kadian (morphine sulfate), which have very different uses from Kapidex and from each other.

[FDA Announces Possible Safety Concern for HIV Drug Combination](#) (Feb. 23)

The FDA announced preliminary data suggesting that Invirase (saquinavir) in combination with Norvir (ritonavir) may have potentially important adverse effects on the heart

[Ongoing Review of Avandia \(rosiglitazone\) and Cardiovascular Safety](#) (Feb. 22)

The U.S. Food and Drug Administration (FDA) is reviewing data, submitted in August 2009, from a large, long-term clinical study on possible risks with the diabetes drug, Avandia (rosiglitazone).

[FDA Announces New Safety Controls for Long-Acting Beta Agonists, Medications Used to Treat Asthma](#) (Feb. 18)

The FDA announced that drugs in the class of long-acting beta agonists (LABAs) should never be used alone in the treatment of asthma in children or adults. Manufacturers will be required to include this warning in the product labels of these drugs, along with taking other steps to reduce the overall use of these medications.

[FDA Warns about Serious Side Effects from Maalox Product Mix-Ups](#) (Feb. 17)

The FDA warned consumers about the potential for serious side effects from mistakenly using *Maalox Total Relief* instead of other *Maalox* products. The two products are intended for the relief of different symptoms and contain different active ingredients.

[FDA Announces New Safety Plan for Agents Used to Treat Chemotherapy-Related Anemia](#) (Feb. 16)

The FDA approved a risk management program to inform healthcare providers and their patients about the risks of a class of drugs called Erythropoiesis-Stimulating Agents (ESAs). For patients with cancer, the program is also designed to help ensure the appropriate administration of these drugs, which they receive to treat anemia that can occur as a result of chemotherapy.

For more product safety information please visit our [MedWatch](#) website.

## **PRODUCT APPROVALS:**

### [FDA Approves Asclera to Treat Small Varicose Veins](#) (Mar. 30)

The FDA approved Asclera (polidocanol) injection for the treatment of small types of abnormally swollen or twisted veins called varicose veins. Although they usually occur in the legs, varicose veins also can form in other parts of the body. Factors such as genetics, age, female gender, pregnancy, obesity, and prolonged periods of standing may increase the risk for varicose veins.

### [FDA Approves New Use of Xifaxan for Patients with Liver Disease](#) (Mar. 24)

The FDA approved the use of Xifaxan for reduction in the risk of the recurrence of overt hepatic encephalopathy (HE) in patients with advanced liver disease. This is a new use for Xifaxan (rifaximin), a drug that has been approved for the treatment of traveler's diarrhea. Hepatic encephalopathy is a worsening of brain function that can occur in patients whose liver can no longer remove toxins from the blood. Increased levels of ammonia in the blood are thought to play a role in the development of HE, and Xifaxan works by reducing these levels.

### [FDA Approves Drug to Treat Condition That Causes Elevated Ammonia Levels](#) (Mar. 18)

The FDA approved Carbaglu (carglumic acid) Tablets to treat a condition that results in too much ammonia in the blood. The condition, N-acetylglutamate synthase or NAGS deficiency, is an extremely rare, genetic disorder that can be present in babies soon after birth. NAGS deficiency and the resulting elevated levels of ammonia (hyperammonemia) can be fatal if it is not detected and treated rapidly. DNA testing can confirm the diagnosis of NAGS.

### [FDA Approves First Totally Implanted Hearing System](#) (Mar. 17)

The FDA announced the approval of the Esteem – an implanted hearing system used to treat moderate to severe sensorineural hearing loss, a type of permanent hearing loss.

### [FDA Approves Botox to Treat Spasticity in Flexor Muscles of the Elbow, Wrist and Fingers](#) (Mar. 9)

The FDA approved Botox (onabotulinumtoxin A) to treat spasticity in the flexor muscles of the elbow, wrist, and fingers in adults. Spasticity is common after stroke, traumatic brain injury, or the progression of multiple sclerosis.

### [FDA Approves First Generic Tamsulosin to Treat Enlarged Prostate Gland](#) (Mar. 2)

The FDA approved the first generic version of Flomax Capsules 0.4 mg (tamsulosin hydrochloride) to treat benign prostatic hyperplasia (BPH), a condition in which an enlarged prostate gland causes problems with urination.

### [FDA Approves Therapy to Treat Gaucher Disease](#) (Feb. 26)

The FDA approved velaglucerase alfa for injection (VPRIV) to treat children and adults with a form of the rare genetic disorder Gaucher disease.

[FDA Approves Pneumococcal Disease Vaccine with Broader Protection](#) (Feb. 24)

The FDA approved Prevnar 13, a pneumococcal 13-valent conjugate vaccine for infants and young children ages 6 weeks through 5 years. Prevnar 13 will be the successor to Prevnar, the pneumococcal 7-valent conjugate vaccine licensed by the FDA in 2000 to prevent invasive pneumococcal disease (IPD) and otitis media.

[FDA Approves Rituxan to Treat Chronic Lymphocytic Leukemia](#) (Feb. 18)

The FDA approved Rituxan (rituximab) to treat certain patients with chronic lymphocytic leukemia (CLL), a slowly progressing blood and bone marrow cancer.

For more information on drug approvals, please visit [Drugs@FDA](#)

**ANNOUNCEMENTS:**

[New Article for Health Professionals: FDA's Transparency Initiative](#) (Mar. 31)

The article describes the FDA's Transparency Initiative, including an update on the first phase's implementation. It also discusses how the health professional community can participate in the initiative.

[FDA MedWatch Mobile Text Messaging](#)

The FDA recently launched a new MedWatch Safety Information mobile text message program. The content of the text messages will consist of alerts that provide timely new safety information on human drugs, medical devices, and related safety topics. The messages contain actionable information that may impact both treatment and diagnostic choices for healthcare professional and patient. To subscribe to the pilot, text FDA to 87000. Subscribers can expect to receive approximately three to five text messages a week during the six-month pilot. Standard text messaging rates will apply.

**RESOURCES:**

[FDA Patient Safety News](#)

A video news show for health professionals

[FDA Basics](#)

Each month, different Centers and Offices at FDA will host an online session where the public can ask questions to senior FDA officials about a specific topic or just listen in to learn more about FDA.

[Access to Investigational Drugs](#) – Webinar Materials

Expanded access, sometimes called "compassionate use," is the use of an investigational drug outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options.