

## FDA AGENCY REPORT – APRIL 2011

Here is a summary of recent product safety, product approvals and announcements 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:

#### [FDA Warns Consumers to Stop Using Soladek Vitamin Solution](#) (Mar 28)

FDA is warning consumers to stop using Soladek, a vitamin-solution product marketed by Indo Pharma, S.A., of the Dominican Republic, because the product may contain dangerously high levels of vitamins A and D.

#### [Lilly Announces Important Action Regarding Recall of Alcohol Prep Pads Made by Triad Group Included in Forteo Starter Kits](#) (Mar 17)

Eli Lilly and Company announced that patients should not use the alcohol prep pads made by the Triad Group that are contained in the black starter kits for Forteo® [teriparatide (rDNA origin) injection] in the United States. The Tri-ad Group is recalling the alcohol prep pads due to potential contamination with the bacteria, *Ba-cillus cereus*, which could result in life threatening infections, especially in at-risk populations, including immune suppressed and surgical patients.

#### [FDA: Risk of oral birth defects in children born to mothers taking topiramate](#) (Mar 4)

New data suggest that the drug Topamax (topiramate) and its generic versions increase the risk for the birth defects cleft lip and cleft palate in babies born to women who use the medication during pregnancy.

#### [FDA modifies boxed warning for pulmonary arterial hypertension drug Letairis](#) (Mar 4)

The FDA announced that monthly liver enzyme tests are no longer required for those taking Letairis tablets (ambrisentan), used to treat high blood pressure in the vessels that carry blood to the lungs (pulmonary arterial hypertension, or PAH).

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

### PRODUCT APPROVALS:

#### [FDA approves new treatment for a type of late-stage skin cancer](#) (Mar 25)

FDA approved Yervoy (ipilimumab) to treat patients with late-stage (metastatic) melanoma, the most dangerous type of skin cancer.

#### [FDA approves Zostavax vaccine to prevent shingles in individuals 50 to 59 years of age](#) (Mar 24)

FDA approved the use of Zostavax, a live attenuated virus vaccine, for the prevention of shingles in individuals 50 to 59 years of age. Zostavax is already approved for use in individuals 60 years of age and older.

[FDA approves imaging agent for central nervous system scans](#) (Mar 15)

The FDA approved Gadavist (gadobutrol), a gadolinium-based contrast agent, for use in patients undergoing magnetic resonance imaging (MRI) of the central nervous system.

[FDA approves device to maintain blood flow during artery bypass brain surgery](#) (Mar 10)

The FDA approved a surgical kit that allows neurosurgeons to reroute blood flow around an aneurysm or a tumor in the brains of patients at greater risk of stroke during standard bypass surgery.

[FDA approves Benlysta to treat lupus](#) (Mar 9)

The FDA approved Benlysta (belimumab) to treat patients with active, autoantibody-positive lupus (systemic lupus erythematosus) who are receiving standard therapy, including corticosteroids, antimalarials, immunosuppressives, and nonsteroidal anti-inflammatory drugs.

- FDA hosted a health professional briefing for belimumab on March 14, 2011. A replay of the teleconference is available until April 14, 2011, by calling 866-513-4388.

[FDA approves new drug to treat chronic obstructive pulmonary disease](#) (Mar 1)

The FDA approved Daliresp (roflumilast), a pill taken daily to decrease the frequency of flare-ups (exacerbations) or worsening of symptoms from severe chronic obstructive pulmonary disease (COPD).

- FDA hosted a health professional briefing for roflumilast on March 9, 2011. A replay of the teleconference is available until April 9, 2011, by calling 800-728-5840.

For information on drug approvals, please visit [Drugs@FDA](mailto:Drugs@FDA).

**ANNOUNCEMENTS:**

[FDA Issues Statement on Makena](#) (Mar 30)

On February 3, 2011, the U.S. Food and Drug Administration approved the drug Makena (hydroxyprogesterone caproate) for the reduction of the risk of certain preterm births in women who have had at least one prior preterm birth.

[Primatene Mist With Chlorofluorocarbons No Longer Available After Dec. 31, 2011](#)  
(Mar 16)

The only over-the-counter asthma inhaler sold in the United States will no longer be available next year as part of an international agreement to stop the use of substances that damage the environment.

[Beware of Fraudulent Weight-Loss ‘Dietary Supplements’](#) (Mar 15)

FDA has found weight-loss products tainted with the prescription drug ingredient sibutramine. This ingredient was in an FDA-approved drug called Meridia, which was removed from the market in October 2010 because it caused heart problems and strokes. FDA has also found other prescription drug ingredients that have been removed from the market or never approved at all.

[Beware of Fraudulent ‘Dietary Supplements’](#) (Mar 15)

Federal regulators continue to warn consumers about tainted, dangerous products that are marketed as dietary supplements. These fraudulent products can cause serious injury or even death.

[FDA prompts removal of unapproved drugs from market](#) (Mar 2)

The FDA took action against companies that manufacture, distribute, or market certain unapproved prescription oral cough, cold, and allergy products. The affected products cannot be legally marketed in the United States. Unapproved prescription cough, cold, and allergy drug products have not been evaluated by the FDA for safety, effectiveness, and quality. People may be at greater risk when using these products than when using FDA-approved prescription drugs or drugs that are appropriately marketed over-the-counter (OTC).

[Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging](#)

Through the [Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging](#)<sup>1</sup>, FDA is advocating the universal adoption of two principles of radiation protection: appropriate justification for ordering each procedure, and careful optimization of the radiation dose used during each procedure.

**RESOURCES:**

[MedWatch Safety Information Resources for Busy Physicians](#)

A video discussing Medwatch Safety Alerts

[FDA Counterfeit Medicine Page Updated](#)

Counterfeit medicine is fake medicine. It may be contaminated or contain the wrong or no active ingredient. Counterfeit drugs are illegal and may be harmful to your health.

[For Health Professionals](#) - Additional information for Health Professionals may be found on FDA’s Health Professional website.

[MedWatch Safety Alerts for Human Medical Products](#)

Your FDA gateway for finding clinically important safety information and reporting serious problems with human medical products.

[FDA Drug Info Rounds](#)

A series of training videos for practicing clinical and community pharmacists.

[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.

**Submitted by CDR Janelle Derbis, PharmD, Office of the Commissioner, Office of Special Health Issues**