

FDA AGENCY REPORT – MAY 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:

[Safety update on Progressive Multifocal Leukoencephalopathy associated with Tysabri \(natalizumab\)](#) (Apr 22)

FDA continues to evaluate the risk of progressive multifocal leukoencephalopathy (PML), a rare but serious brain infection, associated with use of Tysabri (natalizumab) for the treatment of multiple sclerosis and Crohn's disease. FDA has updated the Tysabri label to give new information about the size of this risk, as well as to include new safety information about patients who have taken other drugs that suppress the immune system, who may be at a higher risk for PML.

[Long-Acting Beta-Agonists \(LABAs\): New Safe Use Requirements](#) (Apr 15)

To further evaluate the safety of LABAs when used in combination with inhaled corticosteroids for the treatment of asthma, FDA is requiring the manufacturers of LABAs to conduct five randomized, double-blind, controlled clinical trials comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone. The clinical trials will begin in 2011 and FDA expects to receive results in 2017.

[Lansoprazole Delayed-Release Orally Disintegrating Tablets by Teva Pharmaceuticals: Letter to Healthcare Professionals - Clogged, Blocked Oral Syringes and Feeding Tubes](#) (Apr 15)

FDA has received reports that Teva's lansoprazole delayed-release orally disintegrating tablet has clogged and blocked oral syringes and feeding tubes, including both gastric and jejunostomy types, when the drug is administered as a suspension through these devices. The tablets may not fully disintegrate when water is added to them and/or they may disintegrate but later form clumps. These clumps can adhere to the inside walls of oral syringes and feeding tubes. In some cases, patients have had to seek emergency medical assistance and their feeding tubes have had to be unclogged or removed and replaced.

[Tumor Necrosis Factor \(TNF\) blockers, Azathioprine and/or Mercaptopurine: Update on Reports of Hepatosplenic T-Cell Lymphoma in Adolescents and Young Adults](#) (Apr 14)

FDA continues to receive reports of a rare cancer of white blood cells (known as Hepatosplenic T-Cell Lymphoma, primarily in adolescents and young adults being treated for Crohn's disease and ulcerative colitis with medicines known as tumor necrosis factors blockers, as well as with azathioprine, and/or mercaptopurine. TNF blockers include Remicade (infliximab), Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab pegol) and Simponi (golimumab).

[Benicar \(olmesartan\): Ongoing Safety Review](#) (Apr 14)

After reviewing the results of the ROADMAP and ORIENT trials, FDA has determined that the benefits of Benicar continue to outweigh its potential risks when used for the treatment of patients with high blood pressure according to the drug label. Benicar is not recommended as a treatment to delay or prevent protein in the urine (microalbuminuria) in diabetic patients.

[March: MedWatch Monthly Safety Labeling Changes](#) (Apr 12)

Monthly Safety Labeling Changes includes 55 products with revisions to Boxed Warning, Contraindications, Warnings, Precautions, Adverse Reactions, or Patient Package Insert/Medication Guide sections of Prescribing Information.

[Ongoing safety review of Revlimid \(lenalidomide\) and possible increased risk of developing new malignancies](#) (Apr 8)

FDA is informing the public that we are aware of results from clinical trials conducted inside and outside the United States that found that patients treated with Revlimid (lenalidomide) may be at an increased risk of developing new types of cancer compared to patients who did not take the drug.

[FDA continues to receive reports of a rare, but serious and potentially fatal adverse effect with the use of benzocaine sprays for medical procedures](#) (Apr 7)

FDA is alerting healthcare professionals that the Agency continues to receive reports of methemoglobinemia, a serious and potentially fatal adverse effect, associated with benzocaine sprays. These sprays are used during medical procedures to numb the mucous membranes of the mouth and throat.

[Reports of a rare, but serious and potentially fatal adverse effect with the use of over-the-counter \(OTC\) benzocaine gels and liquids applied to the gums or mouth](#) (Apr 7)

FDA is warning the public that the use of benzocaine, the main ingredient in over-the-counter (OTC) gels and liquids applied to the gums or mouth to reduce pain, is associated with a rare, but serious condition. This condition is called methemoglobinemia and results in the amount of oxygen carried through the blood stream being greatly reduced. In the most severe cases, methemoglobinemia can result in death.

[Yervoy \(ipilimumab\): Risk Evaluation and Mitigation Strategy \(REMS\) - Severe Immune-Mediated Adverse Reactions](#) (Apr 6)

Bristol-Myers Squibb informed healthcare professionals about the REMS, developed in collaboration with FDA, that is required to ensure that the benefits of Yervoy outweigh the risks of severe and fatal immune-mediated adverse reactions.

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

PRODUCT APPROVALS:

[FDA approves the first vaccine to prevent meningococcal disease in infants and toddlers](#) (Apr 22)

FDA approved the use of Menactra in children as young as 9 months for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135. Menactra already is approved for use in people ages 2 through 55 years.

[FDA approves Rituxan to treat two rare disorders](#) (Apr 19)

FDA approved Rituxan (rituximab), in combination with glucocorticoids, to treat patients with Wegener's granulomatosis and microscopic polyangiitis, two rare disorders that cause blood vessel inflammation (vasculitis).

- FDA hosted a health professional briefing to discuss the Rituxan approval on April 20. A replay of the briefing is available until May 20, 2011. To hear the replay dial 866-435-1322.

[FDA approves new medical device for form of brain cancer](#) (Apr 15)

FDA recently approved the NovoTTF-100A System, a new device to treat adults with glioblastoma multiforme that recurs or progresses after receiving chemotherapy and radiation therapy.

[FDA approves Actemra to treat rare form of juvenile arthritis](#) (Apr 15)

FDA approved Actemra (tocilizumab), given alone or in combination with methotrexate, for the treatment of active systemic juvenile idiopathic arthritis in children ages 2 years and older.

FDA hosted a health professional briefing to discuss the Actemra approval on April 20. A replay of the briefing is available until May 20, 2011. To hear the replay, dial 800-964-3454.

[FDA permits marketing of first test to help diagnose dengue fever](#) (Apr 8)

FDA allowed marketing of the first test to help diagnose people with signs and symptoms of dengue fever or dengue hemorrhagic fever, a leading cause of illness and death in the tropics and subtropics.

[FDA approves Horizant to treat restless legs syndrome](#) (Apr 6)

FDA approved Horizant Extended Release Tablets (gabapentin enacarbil), a once-daily treatment for moderate-to-severe restless legs syndrome (RLS).

[FDA approves new treatment for rare form of thyroid cancer](#) (Apr 6)

FDA approved vandetanib to treat adult patients with late-stage (metastatic) medullary thyroid cancer who are ineligible for surgery and who have disease that is growing or causing symptoms.

[FDA approves new device to treat brain aneurysms](#) (Apr 6)

FDA approved a new device that provides neurointerventional surgeons with another tool to treat brain aneurysms without performing open surgery.

For information on drug approvals, please visit Drugs@FDA.

ANNOUNCEMENTS:

[Don't Be Tempted to Use Expired Medicines](#) (Apr 25)

Using expired medical products is risky and possibly harmful to your health. [National Take Back Initiative](#) scheduled for April 30, 2011.

[FDA warns companies to stop making MRSA claims for over-the-counter products](#)

(Apr 20)

FDA issued four warning letters to companies that manufacture and market over-the-counter drug products, including hand sanitizers, that claim to prevent infection from methicillin-resistant Staphylococcus aureus bacteria (MRSA).

[FDA Acts to Reduce Harm from Opioid Drugs](#) (Apr 19)

Opioids are at the center of a major public health crisis of addiction, misuse, abuse, overdose and death. FDA is taking action to protect patients from serious harm due to these drugs. This action represents a careful balance between continued access to these necessary medications and stronger measures to reduce their risks.

- FDA hosted a technical briefing on April 20, 2011 to discuss the opioid REMS. [Podcast and Transcript on Technical Briefing](#)
- [Post-Approval REMS Notification letter \(PDF - 61KB\)](#)

[FDA acts to prevent contamination problems with Triad antiseptic products](#) (Apr 6)

U.S. Marshals, at the request of FDA, have seized more than \$6 million in products distributed by Triad Group Inc., at the company's facility in Hartland, Wis.

[FDA launches consumer-friendly Web search for consumers during recalls](#) (Apr 4)

Consumers can search for food and other product recalls easier and quicker on FDA's website than previously. The FDA Food Safety Modernization Act (FSMA) signed into law in January by President Obama called for a more consumer-friendly recall search engine.

[FDA proposes draft menu and vending machine labeling requirements, invites public to comment on proposals](#) (Apr 1)

FDA issued two proposed regulations regarding calorie labeling on menus and menu boards in chain restaurants, retail food establishments, and vending machines. The FDA invites input on the proposed regulations by visiting <http://www.regulations.gov>¹.

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