

FDA AGENCY REPORT – AUGUST 2010

Here is a summary of recent product safety, product approvals, announcements, Resources and upcoming meetings 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 Drug Safety Communication: Serious medication errors from intravenous administration of nimodipine oral capsules](#) (Aug 2)

FDA is alerting healthcare professionals that nimodipine capsules should be given ONLY by mouth or through a feeding tube (nasogastric tube). This oral medication should NEVER be given by intravenous administration.

[Lundbeck Inc. Announces the Voluntary Nationwide Recall of Two Lots of NeoProfen \(ibuprofen lysine\) Injection Recall will Result in Temporary Product Shortage](#) (July 30)

Lundbeck Inc. has voluntarily recalled two lots of NeoProfen (ibuprofen lysine) Injection that failed to meet a visible particulate quality requirement. These two lots are the only lots currently available to prescribers and therefore the recall will result in a temporary drug shortage. This voluntary recall is the result of the company's inspections of the two product lots of NeoProfen.

[FDA Warns Consumers, Pharmacists, and Wholesalers Not to Use Stolen Advair Diskus Inhalers](#) (July 16)

The FDA warned the public that certain Advair Diskus inhalers stolen from a distribution warehouse in 2009 have been found in some pharmacies. The safety and effectiveness of the stolen inhalers cannot be assured and they should not be used.

[FDA Reviews the Safety of Angiotensin Receptor Blockers and Potential for Small Increased Risk of Cancer](#) (July 15)

FDA is conducting a review of the class of medications known as angiotensin receptor blockers (ARBs) after a recently published study suggested they may be associated with a small increased risk of cancer.

[FDA Issues Requirements for Baxter Healthcare Infusion Pump Recall](#) (July 13)

Company must provide transition guide for facilities using Colleague infusion pumps
FDA required Baxter Healthcare Corp. to take specific steps to carry out the April 2010 recall of all Colleague Volumetric Infusion Pumps (CVIP) and to provide customers with a refund, a replacement pump, or lease termination.

[Arava \(leflunomide\): Boxed Warning - Risk of Severe Liver Injury](#) (July 13)

FDA is adding information on severe liver injury to the Boxed Warning of Arava (leflunomide) a drug used to treat rheumatoid arthritis - to highlight the risk of severe liver injury in patients using this drug and how this risk may be reduced.

[Air- or Gas-Pressurized Spray Devices: Risk of Air or Gas Embolism](#) (July 9)

FDA has received reports of air or gas embolism occurring during or immediately after application of hemostatic drug or biological products using air- or gas-pressurized sprayers.

[FDA Warns of Risks with Unapproved Use of Malaria Drug Qualaquin](#) (July 8)

Serious side effects reported when used to treat or prevent night time leg cramps
FDA warned that the unapproved use of the malaria drug Qualaquin (quinine sulfate) to treat night time leg cramps has resulted in serious side effects and prompted the manufacturer to develop a risk management plan aimed at educating health care professionals and patients about the potential risks.

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

PRODUCT APPROVALS:

[FDA Approves Vaccines for the 2010-2011 Influenza Season](#) (July 30)

The FDA announced that it has approved vaccines for the 2010-2011 influenza season in the United States. Seasonal influenza vaccine protects against three strains of influenza, including the 2009 H1N1 influenza virus, which caused the 2009 pandemic. Last year because the 2009 H1N1 virus emerged after production began on the seasonal vaccine, two separate vaccines were needed to protect against seasonal flu and the 2009 H1N1 pandemic flu virus, but this year, only one vaccine is necessary.

[FDA Approves Drug for Chronic Drooling in Children](#) (July 28)

The FDA approved Cuvposa (glycopyrrolate) Oral Solution to treat chronic severe drooling caused by neurologic disorders in children ages 3 years to 16 years. Drooling is normal in infants. But a significant proportion of the developmentally disabled population experiences drooling caused primarily by neuromuscular dysfunction that makes it hard to swallow. Cuvposa reduces drooling by lowering the volume of saliva produced.

[FDA Approves First Generic Enoxaparin Sodium Injection](#) (July 23)

The FDA approved the first generic version of Lovenox (enoxaparin sodium injection), an anti-coagulant drug used for multiple indications including prevention of deep vein thrombosis (DVT), a potentially deadly blood clotting condition.

[FDA Approves First Implantable Miniature Telescope to Improve Sight of AMD patients](#) (July 6)

FDA announced it has approved the Implantable Miniature Telescope (IMT) to improve vision in some patients with end-stage age-related macular degeneration (AMD).

[FDA Approves Rapid Test for Antibodies to Hepatitis C Virus](#) (June 25)

FDA announced approval of the first rapid blood test for antibodies to the hepatitis C virus (HCV) for individuals 15 years and older.

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

ANNOUNCEMENTS:

[Safe Use of Long-Acting Beta-Agonists](#) (July 16)

FDA Drug Info Rounds pharmacists discuss the new recommendations in the drug labels of Long-Acting Beta-Agonists (LABAs), and provide ways pharmacists can help patients use LABAs safely in the treatment of asthma.

[The Past, Present, and Future of FDA Human Drug Regulation](#)

The Center for Drug Evaluation and Research has updated the popular continuing education program *Drug Review and Related Activities in the United States* and has renamed the updated program to reflect legislative changes and improved operations. The new title is *The Past, Present, and Future of FDA Human Drug Regulation*.

UPCOMING MEETINGS:

[Drug Safety and Risk Management Advisory Committee Meeting Announcement](#)

DATE: September 14, 2010

TIME: 8:00 a.m. – 5:00 p.m.

LOCATION: The Marriott Inn and Conference Center/University of Maryland, University College (UMUC), The Ballrooms, 3501 University Blvd. East, Adelphi, Maryland

CONTACT: Elaine Ferguson, **Through June 8, 2010:** c/o Melanie Whelan, Phone: 301-827-7001, Melanie.Whelan@fda.hhs.gov

Beginning June 9, 2010: c/o Christine Shipe, Phone: 301-796-9001, E-mail: Elaine.Ferguson@fda.hhs.gov

The committee will discuss the abuse potential of the drug dextromethorphan and the public health benefits and risks of dextromethorphan use as a cough suppressant in prescription and nonprescription drug products. The Department of Health and Human Services received a request from the Drug Enforcement Administration for a scientific and medical evaluation and scheduling recommendation for dextromethorphan in response to the increased incidence of abuse, especially among adolescents.

Please visit [FDA's Advisory Committee page](#) to obtain advisory committee meeting agendas, briefing materials, and meeting rosters prior to the meetings. You may also visit this page after meetings to obtain transcripts, presentations, and voting results. For additional information on other agency meetings please visit [Meetings, Conferences, & Workshops](#).

RESOURCES:

Articles

[CFC metered-dose inhalers: Counseling patients on the phase-out, Pharmacy Today, June 2010 \(PDF - 89KB\)](#)

An article describing the chlorofluorocarbon (CFC) metered-dose inhalers (MDIs) phase out and the role pharmacists can play in educating patients about alternative treatments.

Please visit [Articles of Interest](#) to access articles produced by FDA and written for a health professional audience. These articles include FDA News for Health Professionals articles, as well as articles that were published in health professional journals.

Other Resources

[FDA Drug Info Rounds](#)

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

[FDA Patient Safety News](#)

FDA Patient Safety News is a televised series for health care personnel, carried on satellite broadcast networks aimed at hospitals and other medical facilities across the country. It features information on new drugs, biologics and medical devices, on FDA safety notifications and product recalls, and on ways to protect patients when using medical products.

[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.