

FDA AGENCY REPORT – SEPTEMBER 2010

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

[FDA Drug Safety Communication: Increased risk of death with Tygacil \(tigecycline\) compared to other antibiotics used to treat similar infections](#) (Sep. 1)

The FDA is reminding healthcare professionals of an increased mortality risk associated with the use of the intravenous antibacterial Tygacil (tigecycline) compared to that of other drugs used to treat a variety of serious infections.

[Multi-Med, Inc., 22 Gauge x 1 inch Straight and Right Angle Huber Needles and Navilyst Medical Inc., Vaxcel Implantable Vascular Access Systems Containing Huber Needles \(Two Class I Recalls\)](#) (Aug 26)

Huber needles are safety needles used on vascular access ports implanted in patients in need of repeated intravenous therapy. A "coring" Huber needle could damage the implanted port by removing silicone slivers from the access membrane. The defect in the port as a result of coring can cause the ports to leak.

[Ikaria Holdings, INOMAX DS Drug Delivery System](#) (Aug 23)

A component within the pressure switch, which monitors when the drug supply should be replaced, may tear. Risks to the patient may include interruption of drug flow due to an empty cylinder, and/or the time taken to switch to a replacement system.

[Ongoing Safety Review of Stalevo and possible increased cardiovascular risk](#) (Aug 20)

FDA is evaluating clinical trial data that suggest patients taking Stalevo (a combination of carbidopa/levodopa and entacapone) may be at an increased risk for cardiovascular events (heart attack, stroke, and cardiovascular death) compared to those taking carbidopa/levodopa (sold as the combination product, Sinemet).

[Urgent Nationwide Egg Recall](#) (Aug 19)

The current recall of eggs in their shells, or "shell eggs," is part of an ongoing and intensive investigation by local, state, and federal officials into the cause of recent cases of *Salmonella* Enteritidis. This recall affects shell eggs produced by Wright County Egg of Galt, Iowa. FDA and the State of Minnesota identified Hillandale Farms in Iowa as a second potential source of contaminated shell eggs.

[FDA Proposes Withdrawal of Low Blood Pressure Drug](#) (Aug 16)

FDA proposes to withdraw approval of the drug midodrine hydrochloride, used to treat the low blood pressure condition orthostatic hypotension, because required post-approval studies that verify the clinical benefit of the drug have not been done. FDA held a stakeholder teleconference on midodrine, a replay is available at 866-443-1213, pass code 1263.

[FDA: Aseptic Meningitis Risk with Use of Seizure Drug Lamictal](#) (Aug 12)

FDA warns that the drug Lamictal (lamotrigine), approved to treat seizures and bipolar disorder, can cause aseptic meningitis, an inflammation of the protective membranes (meninges) that cover the brain and spinal cord not caused by bacterial infection.

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

PRODUCT APPROVALS:

[FDA approves ella tablets for prescription emergency contraception](#) (Aug 13)

The FDA approved ella (ulipristal acetate) tablets for emergency contraception. The prescription-only product prevents pregnancy when taken orally within 120 hours (five days) after a contraceptive failure or unprotected intercourse. It is not intended for routine use as a contraceptive.

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

ANNOUNCEMENTS:

[Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication](#) (Aug 26)

CDC and FDA have noted a progressive increase in the reports of bloodborne infection transmission over the past 10 to 15 years (primarily hepatitis B virus), resulting from the shared use of fingerstick and POC blood testing devices.

[Study: Presence of murine leukemia virus found in CFS Patients, others](#) (Aug 23)

Researchers have found murine leukemia viruses (MLV) related gene sequences in blood samples collected from patients diagnosed with chronic fatigue syndrome (CFS) and some healthy blood donors, according to a study published online today by the scientific journal Proceedings of the National Academy of Sciences (PNAS).

[Registries Help Moms Measure Medication Risks](#)

With studies showing the average woman takes from three to five medications while pregnant, the Food and Drug Administration (FDA) encourages drug makers and moms-to-be to participate in pregnancy registry studies that track the risks from drugs taken during pregnancy or breastfeeding.

The Center for Devices and Radiological Health (CDRH) recently developed a new type of communication. Informally referred to as a DUSTi (for **Device Use Safety Tip**), these short reminders are based on situations (reports of injuries or "close calls") that occurred because labeling instructions were not followed. These communications will not present new information; rather they will highlight existing labeling information that may not be uniformly recognized, understood or followed. The first DUSTi, Air or Electric Dermatology Instruments - Medical Device Safety Tips, is available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm219563.htm>

[FDA Issues Assessments of the 510\(k\) Program and Use of Science in Decision-Making](#)
(Aug 4)

The FDA issued two comprehensive evaluations containing recommendations that address three key objectives of the agency's public health mission as it relates to medical devices – foster device innovation, create a more predictable regulatory environment, and enhance device safety.

[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

[Development and Distribution of Patient Medication Information for Prescription Drugs: Public Hearing](#)

DATE: September 27-28, 2010

TIME: 8:30 a.m. to 4:30 p.m.

LOCATION: FDA White Oak Campus, 10903 New Hampshire Ave, Building 31, Room 1503, Spring, Maryland 20993

The FDA is announcing a 2-day public hearing to obtain input on a new framework for development and distribution of patient medication information (PMI), which is provided to patients who are prescribed drug products.

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

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.