

## FDA AGENCY REPORT – AUGUST 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:

#### [CardioGen-82 PET Scan: Increased Radiation Exposure \(July 15\)](#)

FDA notified the public and the medical imaging community about the potential for inadvertent, increased radiation exposure in patients who underwent or will be undergoing cardiac positron emission tomography (PET) scans with rubidium (Rb)-82 chloride injection from CardioGen-82 manufactured by Bracco Diagnostics, Inc.

#### [FDA: Surgical placement of mesh to repair pelvic organ prolapse poses risks \(July 13\)](#)

FDA issued an updated safety communication warning health care providers and patients that surgical placement of mesh through the vagina to repair pelvic organ prolapse may expose patients to greater risk than other surgical options.

- A stakeholder teleconference concerning the use of surgical mesh for pelvic organ prolapse was held on July 14, 2011. A replay of the call is available at 800-843-4802 until August 14, 2011.

#### [Important safety changes to the influenza drug Tamiflu \(oseltamivir phosphate\) for oral suspension \(July 11\)](#)

FDA is informing the public of important product safety changes to the influenza drug Tamiflu (oseltamivir phosphate) for oral suspension.

- [MedWatch Alert](#)
- [Consumer Update \(printable\)](#)

#### [Nulojix \(belatacept\): Risk Evaluation and Mitigation Strategy \(REMS\) \(July 7\)](#)

Increased Risk of Post-transplant Lymphoproliferative Disorder, predominantly involving the Central Nervous System, and Progressive Multifocal Leukoencephalopathy (PML)

#### [FDA modifies dosing recommendations for Erythropoiesis-Stimulating Agents \(June 24\)](#)

FDA recommended more conservative dosing guidelines for Erythropoiesis-Stimulating Agents when used to treat anemia in patients with chronic kidney disease because of the increased risks of cardiovascular events such as stroke, thrombosis, and death

#### [FDA provides updated safety data on silicone gel-filled breast implants \(June 22\)](#)

FDA released a report updating the clinical and scientific information for silicone gel-filled breast implants, including preliminary safety data from studies conducted by the manufacturers as a condition of their November 2006 approval.

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

## **PRODUCT APPROVALS:**

### [FDA approves vaccines for the 2011-2012 influenza season \(July 18\)](#)

FDA announced that it has approved the 2011-2012 influenza vaccine formulation for all six manufacturers licensed to produce and distribute influenza vaccine for the U.S.

### [FDA approves Boostrix to prevent tetanus, diphtheria, and pertussis in older people \(July 8\)](#)

FDA approved Boostrix vaccine to prevent tetanus, diphtheria, and pertussis in people ages 65 and older. Boostrix, which is given as a single-dose booster shot, is the first vaccine approved to prevent all three diseases in older people.

### [FDA approves Arcapta Neohaler to treat chronic obstructive pulmonary disease \(July 1\)](#)

FDA approved Arcapta Neohaler (indacaterol inhalation powder) for the long term, once-daily maintenance bronchodilator treatment of airflow obstruction in people with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema.

- A health professional briefing concerning the recently approved drug product, Arcapta Neohaler was held on July 13, 2011. A replay of the call is available at 800-754-7902 until August 13, 2011.

### [FDA approves Xarelto to reduce risk of blood clots after hip, knee replacements \(July 5\)](#)

FDA approved Xarelto (rivaroxaban) to reduce the risk of blood clots, deep vein thrombosis, and pulmonary embolism following knee or hip replacement surgery.

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

## **ANNOUNCEMENTS:**

### [FDA unveils final cigarette warning labels \(June 21\)](#)

FDA unveiled the nine graphic health warnings required to appear on every pack of cigarettes sold in the United States and in every cigarette advertisement.

## **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**