

FDA AGENCY REPORT – OCTOBER 2010

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:

[Amgen Initiates Voluntary Nationwide Recall Of Certain Lots Of Epogen[®] And Procrit[®] \(Epoetin Alfa\)](#) (Sep 24)

Amgen announced that certain lots of EPOGEN[®] and PROCIT[®] (Epoetin alfa) vials are being voluntarily recalled from specialty distributors, wholesalers, pharmacies and healthcare providers as a precaution.

[FDA significantly restricts access to the diabetes drug Avandia](#) (Sep 23)

FDA announced that it will significantly restrict the use of the diabetes drug Avandia (rosiglitazone) to patients with Type 2 diabetes who cannot control their diabetes on other medications. These new restrictions are in response to data that suggest an elevated risk of cardiovascular events, such as heart attack and stroke, in patients treated with Avandia.

[URGENT: Voluntary Market Withdrawal - Octagam \[Immune Globulin Intravenous \(Human\)\] 5% Liquid Preparation](#) (Sep 23)

Effective immediately, Octapharma USA Inc. is initiating a voluntary market withdrawal of ALL lots of octagam[®] [Immune Globulin Intravenous (human)] 5% Liquid Preparation] currently in the US market.

[Abbott Voluntarily Recalls Certain Similac[®] Brand Powder Infant Formulas That Did Not Meet Its Quality Standards](#) (Sept 22)

Abbott is initiating a proactive, voluntary recall of certain Similac-brand, powder infant formulas in the U.S., Puerto Rico, Guam and some countries in the Caribbean.

[Symbiq One and Two-Channel Infusers](#) (Sep 21)

The Symbiq One and Two-Channel Infusers are infusion pumps intended for the delivery of fluids, solutions, drugs, agents, nutritionals, electrolytes, blood and blood products via parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural, or irrigation routes of administration. Hospira sent additional information to customers through an Urgent Product Recall letter on September 13, 2010. Distribution of this product has stopped pending corrective actions.

[FDA reviewing preliminary safety information on Actos \(pioglitazone\)](#) (Sep 17)

FDA announced it has begun a safety review of the diabetes drug Actos (pioglitazone), after receiving preliminary results from a long-term observational study designed to evaluate the risk of bladder cancer associated with use of this drug.

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

ANNOUNCEMENTS:

[Infant Sleep Positioners Pose Suffocation Risk](#) (Sep 29)

FDA and the Consumer Product Safety Commission are warning parents and other caregivers not to put babies in sleep positioning products as two recent deaths underscore concerns about suffocation.

[FDA Issues Final Rule on Safety Information During Clinical Trials](#) (Sep 28)

FDA issued a final rule that clarifies what safety information must be reported during clinical trials of investigational drugs and biologics.

[New dosing recommendations to prevent potential Valcyte \(valganciclovir\) overdose in pediatric transplant patients](#) (Sep 15)

FDA is notifying healthcare professionals of new pediatric dosing recommendations for Valcyte (valganciclovir hydrochloride) oral tablets and oral solution. This change is being made to prevent potential valganciclovir overdosing in children with low body weight, low body surface area, and below normal serum creatinine.

[FDA: New warnings required on use of gadolinium-based contrast agents](#) (Sep 9)

FDA is requiring that gadolinium-based contrast agents (GBCAs) carry new warnings on their labels about the risk of a rare and potentially fatal condition known as nephrogenic systemic fibrosis (NSF), if the drug is administered to certain patients with kidney disease.

[FDA acts against 5 electronic cigarette distributors](#) (Sep 9)

FDA issued warning letters to five electronic cigarette distributors for various violations of the Federal Food, Drug, and Cosmetic Act (FDCA) including unsubstantiated claims and poor manufacturing practices.

[AngioScore Inc. - AngioSculpt "EX" PTCA Scoring Balloon Catheter](#) (Sep 8)

The PTCA catheters may become separated during use in which fragments of the catheter may become lodged in coronary arteries. This may result in serious injuries, including death. The company sent its customers a recall notice addressed to Catheterization Laboratory Managers.

[Recall of Abbott Prism HIV O Plus](#) (Sep 3)

Abbott has seen an increase in customer complaints for calibration failures when PRISM-HIV-1 Group O Positive Assay Control (2) (Symbol: OPC) is out of specification high.

PRODUCT APPROVALS:

[FDA approves combination contraceptive containing a folate](#) (Sep 24)

FDA approved Beyaz tablets, an estrogen/progestin combined oral contraceptive that also contains a folate (levomefolate calcium 0.451 mg).

[FDA approves first oral drug to reduce MS relapses](#) (Sep 22)

FDA approved Gilenya capsules (fingolimod) to reduce relapses and delay disability progression in patients with relapsing forms of multiple sclerosis (MS).

[FDA approves devices for heart failure patients](#) (Sep 16)

FDA approved a new indication for three cardiac resynchronization therapy defibrillators (CRT-D) used to treat certain heart failure patients. The new use is for patients with an abnormality known as left bundle branch block.

[FDA approves new drug for gout](#) (Sep 14)

FDA approved Krystexxa (pegloticase) to treat the painful condition known as gout in adults who do not respond to or who cannot tolerate conventional therapy.

[FDA approves pediatric use of chemical poisoning treatment](#) (Sep 9)

FDA has approved the pediatric use of Protopam Chloride (pralidoxime chloride), a drug used to treat poisoning by organophosphate pesticides and chemicals (e.g., nerve agents). The drug is approved to be administered either by intravenous (IV) or intramuscular (IM) injections.

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