

FDA AGENCY REPORT – OCTOBER 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:

[FDA Drug Safety Communication: Safety review update on the possible increased risk of blood clots with birth control pills containing drospirenone](#) (Sept 26)

FDA is informing the public that it has not yet reached a conclusion, but remains concerned, about the potential increased risk of blood clots with the use of drospirenone-containing birth control pills.

[FDA Drug Safety Communication: Abnormal heart rhythms may be associated with use of Zofran \(ondansetron\)](#) (Sept 15)

FDA is informing the public of an ongoing safety review of the anti-nausea drug Zofran (ondansetron, ondansetron hydrochloride and their generics). Ondansetron may increase the risk of developing abnormal changes in the electrical activity of the heart, which can result in a potentially fatal abnormal heart rhythm.

[Tumor Necrosis Factor-alpha - Drug labels for the Tumor Necrosis Factor-alpha blockers now include warnings about infection with Legionella and Listeria bacteria](#) (Sep 7)

FDA is informing healthcare professionals that the Boxed Warning for the entire class of Tumor Necrosis Factor-alpha (TNFa) blockers has been updated to include the risk of infection from two bacterial pathogens, Legionella and Listeria.

[Saphris \(asenapine maleate\) - Serious allergic reactions reported with the use of Saphris](#) (Sep 1)

FDA is warning the public that serious allergic reactions have been reported with the use of the antipsychotic medication Saphris (asenapine maleate).

[Reclast \(zoledronic acid\) - New contraindication and updated warning on kidney impairment for Reclast](#) (Sep 1)

FDA has approved an update to the drug label for Reclast (zoledronic acid) to better inform healthcare professionals and patients of the risk of kidney (renal) failure.

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

PRODUCT APPROVALS:

[FDA approves Remicade to treat ulcerative colitis in children 6 years and older](#) (Sept 23)

FDA approved Remicade (infliximab) to treat moderately to severely active ulcerative colitis (UC) in children 6 years and older who have had inadequate response to conventional therapy.

[FDA approves Soliris for rare pediatric blood disorder](#) (Sept 23)

FDA approved Soliris (eculizumab) to treat patients with atypical Hemolytic Uremic Syndrome (aHUS), a rare and chronic blood disease that can lead to kidney (renal) failure and is also associated with increased risk of death and stroke.

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

ANNOUNCEMENTS:

[FDA: Over-the-counter asthma inhalers containing chlorofluorocarbons \(CFCs\) will no longer be made or sold after Dec. 31, 2011](#) (Sept 21)

FDA says users of epinephrine inhalers containing chlorofluorocarbons should plan now to get a prescription for a replacement product because these inhalers will not be made or sold after Dec. 31, 2011.

- FDA hosted a stakeholder teleconference concerning the phase-out of Epinephrine CFC Metered-Dose Inhalers on September 21. A replay is available until October 22. To hear the replay, callers can dial 866-501-8768

[New! Availability of Spanish language versions of Drug Safety Communications](#)

CDER's Office of Communications has launched a new pilot program to provide Spanish language versions of the agency's Drug Safety Communications (DSCs). Given various time and review constraints, the Spanish version DSCs will generally follow the English version by about 1-2 weeks. Recent Spanish version DSCs:

[Reclast \(ácido zoledrónico\)](#) - Nueva contraindicación y advertencia actualizada sobre el deterioro renal causado por Reclast (ácido zoledrónico)

[Saphris \(maleato de asenapina\)](#) - Informe sobre reacciones alérgicas graves por el uso de Saphris (maleato de asenapina)

[Antagonistas del factor de necrosis tumoral alfa \(TNF \$\alpha\$ \)](#) - Las etiquetas de los medicamentos antagonistas del factor de necrosis tumoral alfa (TNF α) incluyen ahora advertencias sobre infección con las bacterias Legionella y Listeria

[Consumer Updates:](#)

- [FDA's MedWatch Safety Alerts: August 2011](#)
- [Primatene Mist With Chlorofluorocarbons No Longer Available After Dec. 31, 2011](#)

[FDA announces changes in drug center's oncology office](#) (Sep 12)

FDA announced organizational changes within the office responsible for reviewing all drug and biologic applications for cancer therapies. The Center for Drug Evaluation and Research's (CDER) Office of Oncology Drug Products has been reorganized and renamed the Office of Hematology and Oncology Products (OHOP).

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