

FDA AGENCY REPORT – JANUARY 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: Ongoing safety review of Recombinant Human Growth Hormone \(somatropin\) and possible increased risk of death](#) (Dec 22)

FDA is informing the public that results from a study conducted in France – the Santé Adulte GH Enfant (SAGhE) study—found that persons with certain kinds of short stature (idiopathic growth hormone deficiency and idiopathic or gestational short stature) treated with recombinant human growth hormone during childhood and who were followed over a long period of time, were at a small increased risk of death when compared to individuals in the general population of France.

[Recall of Abbott glucose test strips](#) (Dec 22)

FDA announced the agency is working with Abbott Diabetes Care to recall 359 different lots of glucose test strips marketed under the following brand names:

- Precision Xceed Pro;
- Precision Xtra;
- Medisense Optium;
- Optium;
- OptiumEZ; and
- ReliOn Ultima

[Abnormal heart rhythms associated with use of Anzemet \(dolasetron mesylate\)](#) (Dec 17)

is informing patients and healthcare professionals that the **injection** form of Anzemet (dolasetron mesylate) should no longer be used to prevent nausea and vomiting associated with cancer chemotherapy (CINV) in pediatric and adult patients.

[Tainted products marketed as dietary supplements potentially dangerous](#) (Dec 15)

In a letter sent to dietary supplement manufacturers, the FDA expressed concern about undeclared or deceptively labeled ingredients in products marketed as dietary supplements. These substances include the active ingredients in FDA-approved drugs or their analogs (closely-related drugs), or other compounds, such as novel synthetic steroids, that do not qualify as dietary ingredients.

[Tessalon liquid cough capsules pose risk for young children](#) (Dec 14)

FDA is warning that accidental ingestion of Tessalon (benzonatate) by children younger than 10 years can result in serious side effects or death. Tessalon, approved by the FDA to treat symptomatic relief of cough in patients older than 10, may attract younger children because of the drug's candy-like appearance – a round, liquid-filled gelatin

capsule. The safety and effectiveness of benzonatate in children younger than 10 years has not been established.

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

ANNOUNCEMENTS:

[FDA to require substantial equivalence reviews for new tobacco products](#) (Jan 5)

FDA announced that certain tobacco products introduced or changed after Feb. 15, 2007 must be reviewed by the agency.

[FDA begins process to remove breast cancer indication from Avastin label](#) (Dec 16)

FDA is recommending removing the breast cancer indication from the label for Avastin (bevacizumab) because the drug has not been shown to be safe and effective for that use.

The agency is making this recommendation after reviewing the results of four clinical studies of Avastin in women with breast cancer and determining that the data indicate that the drug does not prolong overall survival in breast cancer patients or provide a sufficient benefit in slowing disease progression to outweigh the significant risk to patients. These risks include severe high blood pressure; bleeding and hemorrhage; the development of perforations (or “holes”) in the body, including in the nose, stomach, and intestines; and heart attack or heart failure.

FDA held a stakeholder call to healthcare professionals and patients advocates on December 16, it is available for replay until February 15, 2011. To hear the replay, callers can dial toll-free 866-357-4215; international callers can dial 203-369-0130. The passcode is 121610.

[FDA issues guidance on public comment procedures at advisory committee meetings](#) (Dec 9)

FDA issued final guidance for people who wish to comment during the agency’s advisory committee meetings. The guidance provides instructions on how to request a time to speak and how FDA staff should respond to requests to speak at the meetings.

[Meetings on User Fee Program for Biosimilar and Interchangeable Biological Product Applications: Request for Notification of Stakeholder Intention to Participate](#) (Dec. 8)

FDA is issuing this notice to request that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify FDA of their intent to participate in consultation meetings relating to the development of a user fee program for biosimilar and interchangeable biological product applications submitted under the Public Health Service Act (PHS Act).

If you intend to participate in stakeholder consultation meetings regarding the development of recommendations for a user fee program for biosimilar and interchangeable biological product applications for FYs 2013 through 2017, please

provide notification by e-mail to BiosimilarsUserFeeProgram@fda.hhs.gov by January 10, 2011.

[FDA Drug Information Video on Drug Shortages](#) (Dec. 1)

FDA's Drug Information Rounds provide information on FDA's role in responding to and mitigating drug shortages.

PRODUCT APPROVALS:

[FDA: Gardasil approved to prevent anal cancer](#) (Dec 22)

FDA approved the vaccine Gardasil for the prevention of anal cancer and associated precancerous lesions due to human papillomavirus (HPV) types 6, 11, 16 and 18 in people ages 9 through 26 years.

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

Other Resources

[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

[FDA MedWatch is now on Twitter!](#) Your FDA gateway for receiving clinically important safety information on human medical products is now on Twitter.

Follow us on Twitter to receive the MedWatch Safety Alerts:
<http://twitter.com/FDAMedWatch>

[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.