U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Drugs

Counterfeit Version of Avastin in U.S. Distribution

Statement Update Issued: July 10. 2012

FDA has issued letters to medical practices in the United States that purchased unapproved medications that may include the counterfeit versions of Avastin or Altuzan. The medical practices purchased unapproved medications from foreign distributors such as Clinical Care, Quality Specialty Products (QSP), Montana Health Care Solutions, and Bridgewater Medical.

Statement Issued: Feb. 14, 2012

FDA sends letters to 19 medical practices about counterfeit product and other unapproved cancer medicines

The U.S. Food and Drug Administration (FDA) is warning health care professionals and patients about a counterfeit version of Avastin 400mg/16mL, which may have been purchased and used by some medical practices in the United States. Avastin is an injectable medicine used to treat cancer and is administered to patients in clinics, hospitals, and doctors' offices. The counterfeit version of Avastin does not contain the medicine's active ingredient, bevacizumab, which may have resulted in patients not receiving needed therapy.

In a related action, FDA has issued letters to 19 medical practices in the United States that purchased unapproved cancer medicines that may include the counterfeit Avastin. The counterfeit version is labeled as Avastin, manufactured by Roche. Roche is the company that manufactures Avastin approved for marketing outside of the United States.

Roche conducted laboratory tests that confirmed the counterfeit version of Avastin. Packages or vials may be counterfeit if they:

- are labeled with Roche as the manufacturer
- display batch numbers that start with B6010, B6011 or B86017

The only FDA-approved version of Avastin for use in the United States is marketed by Genentech (a member company of Roche). The FDA-approved version does not include the Roche logo on the packaging or vials. In addition, Genentech's FDA-approved version of Avastin vials and packaging have a 6-digit numeric batch number and expiration dates in a 3-letter month and 4-digit year format (e.g., JAN 2014). Genentech's Avastin products are safe and effective for their intended uses.

The 19 medical practices in the United States purchased unapproved cancer medicines and, potentially, the counterfeit Avastin, from Quality Specialty Products (QSP), a foreign supplier that may also be known as Montana Health Care Solutions. Volunteer Distribution in Gainesboro, Tennessee is a distributor of QSP's products. FDA has requested that the medical practices stop using any remaining products from these suppliers. FDA cannot ensure the safety or efficacy of any of these unapproved products.

- Letters to Doctors about Risks of Purchasing Medications from Foreign or Unlicensed Suppliers[1]

Based on information to date, FDA has determined that none of the unapproved cancer medicines received by these medical practices from Volunteer Distribution are in shortage in the United States. FDA-approved versions of these medicines are available in adequate supply to meet current demand.

Medical practices that have obtained unapproved products from foreign sources, in particular from Volunteer Distribution and/or QSP, should stop using them and contact the FDA. These products should be retained and securely stored.

To report suspect counterfeit products and other suspect unapproved products obtained from Volunteer Distribution or QSP/Montana Health Care Solutions or other sources:

- Call FDA's Office of Criminal Investigations (OCI) at 800-551-3989, or
- Visit OCI's Web site (www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm[2]), or
- Email - DrugSupplyChainIntegrity@fda.hhs.gov

Health care professionals and consumers are asked to report adverse events related to the use of suspect injectable cancer medicines to the FDA's MedWatch Safety Information and Adverse Event Reporting Program either online, by regular mail, by fax, or by phone. Health care profssionals and consumers can either:

- Complete and submit the report online: www.fda.gov/MedWatch/report.htm[3], or
- Download form[4] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

FDA continues to evaluate this counterfeit medicine situation and we will provide updates.

For information about this counterfeit medicine, see Roche's statement: http://www.gene.com/gene/news/press-releases/press_statements/ps_021412.html[5][6]

For more information about counterfeit medicine:
http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm[7].

Pictures of the counterfeit version of Avastin are shown below:

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