

February 2012

**COUNTERFEIT PRODUCT LABELED AS
AVASTIN® (bevacizumab) IN THE UNITED STATES****IMPORTANT
DRUG
WARNING**

Dear Healthcare Professional:

Genentech, a member of the Roche Group, has been informed that a counterfeit product, labeled as Avastin (bevacizumab), has been distributed in the United States. Upon chemical analyses of the vials, it was confirmed that the counterfeit product does not contain bevacizumab (the active ingredient of Avastin); hence, it should not be used. It is not effective nor safe. Patient safety is Roche and Genentech's primary concern. We are working with the U.S. Food and Drug Administration (FDA) and law enforcement to aid their evaluations, determine the source of the counterfeit drug, and prevent its further distribution.

If you have any product in your possession that you suspect may be counterfeit, or if you suspect a patient may have received counterfeit drug, you should immediately contact the FDA's Office of Criminal Investigations (OCI) at 1-800-551-3989 (<http://www.fda.gov/OCI>) or Genentech's Product Quality Assurance department at 1-800-334-0290.

If you are aware of a patient experiencing any adverse effects that you think may be related to Avastin or to the use of counterfeit drug, please immediately call FDA's MedWatch Program (1-800-FDA-1088) or Genentech's Drug Safety Department at 1-888-835-2555.

As the implications for public health and safety are high, we take the issue of counterfeiting extremely seriously. Roche and Genentech have implemented various approaches to combat counterfeiting that include working with relevant stakeholders to secure the distribution system and implementing special packaging and printing techniques that make counterfeits both more difficult to make and easier to spot. The counterfeit product does not look similar to authentic Avastin that is FDA-approved for the treatment of certain cancers in the United States. The following is true for all authentic Avastin that is FDA-approved for use in the United States:

- All cartons and vials approved for use in the United States have "Genentech" or "Genentech, a member of the Roche Group" printed on the labels;
- The lot number on the carton and vial should be 6 digits with no letters;
- The expiry date is formatted as a 3-letter month and 4-digit year, e.g. JUL 2014;
- The date of manufacture is not printed on the carton or vial;
- All the text on the vial labels, cartons and package inserts is English.

Genentech encourages healthcare providers to purchase Avastin, approved for use in the U.S., through Genentech's authorized wholesalers and specialty distributors. Please see the following page for information on Genentech's authorized wholesalers and specialty distributors and additional information on this topic.

Sincerely,



Hal Barron, M.D., FACC
Chief Medical Officer
Head of Global Product Development
Genentech

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For additional information, please see the following:

Resources:

- Genentech Press Statement, including pictures of authentic and counterfeit product: http://www.gene.com/gene/news/press-releases/press_statements/ps_021412.html
- FDA Counterfeit Notice: <http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm>
- List of authorized Avastin distributors: www.AvastinAccessSolutions.com > select HCP > Type in "Authorized Wholesalers" > Click on "Authorized Specialty Distributors, Wholesalers and Specialty Pharmacies" for the complete list
- Avastin Prescribing and Important Safety Information: www.Avastin.com

Phone numbers:

- FDA's Office of Criminal Investigations (OCI): 1-800-551-3989 (<http://www.fda.gov/OCI>)
- FDA's MedWatch Program: 1-800-FDA-1088
- Genentech's Product Quality Assurance department: 1-800-334-0290
- Genentech's Drug Safety Department: 1-888-835-2555

Authentic Avastin FDA-Approved for Use in the United States



Counterfeit Product

