DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

February 10, 2012

<Dr. Name>
<Address 1>
<Address 2>

Re: Unapproved Versions of Injectable Cancer Medications Could Result in Serious Harm to Your Patients; One Counterfeit Version Found

Dear Dr._____:

According to information received by the Food and Drug Administration (FDA), your medical practice has purchased medications from Quality Specialty Products (QSP), a foreign supplier that may also be known as Montana Health Care Solutions. QSP's products are distributed through Volunteer Distribution based in Gainesboro, Tennessee. Many of the products sold and distributed by these suppliers have not been approved by the FDA. FDA has learned that one of the products is a counterfeit version of Roche's Avastin 400 mg/16 mL. The Agency is very concerned that these products may cause harm to patients because they are unsafe or ineffective.

The packaging or vials of the counterfeit version of Roche's Avastin 400 mg/16mL may list one of the following batch numbers, expiry dates, and/or manufacturing date. Packaging or vials which claim to be Roche's Avastin product with batch numbers that start with B6011 and B86017 should be considered counterfeit. These products that claim to be Roche's Avastin should not be used.

Batch Number	Expiry Date	Manufacturing Date
B6011	---	03.2011
B86017	03.2013	03.2011

The only FDA-approved version of Avastin for use in the U.S. is marketed by Genentech. Genentech's Avastin vials and packaging only have "Genentech", a 6-digit numeric batch number, and expiration dates that are expressed in the following example of month/year format: JAN 2014. Genentech's Avastin products are considered safe and effective.

Any products obtained from Volunteer Distribution and QSP/Montana Health Care Solutions may be from unknown sources, may have unknown ingredients, may be counterfeit, or may not have been manufactured, transported or stored under proper conditions required by U.S. law, regulations, and standards. A high percentage of these products are injectable cancer medications whose quality could be adversely affected if they are not stored or transported under specific temperatures.

FDA conducted a comparison of the list of products purchased through these suppliers and the list of current drug shortages. The agency determined that none of the purchased products are currently in shortage in the U.S. and that FDA-approved versions of the drugs are available in adequate supply to meet current demand.

We request that you cease using and retain and secure all remaining products purchased from QSP and received from Volunteer Distribution or any other unapproved foreign source until further notice. Please do not return the product to the place of purchase at this time. FDA is continuing to evaluate this situation, and we will provide further instructions regarding the disposition of the product at a future date.

On 1/13/2012, FDA issued a notice to health care providers about the risks of purchasing unapproved injectable cancer medications from unlicensed sources. This notice, which includes information on how to identify whether your distributor or the product you receive is legitimate, can be found at http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf

Purchasing these products from a foreign source violates the Federal Food, Drug, and Cosmetic Act (FFDCA) and other federal statutes, rendering these drugs illegal.

Information regarding any criminal activity involving the importation and use of foreign unapproved drugs can be reported to FDA's Office of Criminal Investigations (OCI), www.fda.gov/oci.

Health care providers and patients are asked to report adverse events related to the use of suspect medications to the FDA's MedWatch Safety Information and Adverse Event Reporting Program either online, by regular mail, by fax, or by phone. Heath care providers and patients can either:

- Complete and submit the report online: www.fda.gov/MedWatch/report.htm or
- Download form 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 is committed to promoting and protecting the public health by ensuring that only safe and effective products are available to the American public. Please contact Leigh Verbois at DrugSupplyChainIntegrity@fda.hhs.gov if you have any questions regarding this letter.

Sincerely,

/s/

Thomas J. Christl
Acting Director
Office of Drug Security, Integrity, and Recalls
Office of Compliance
Center for Drug Evaluation and Research

cc: Executive Director, State Medical Board
Executive Director, State Board of Pharmacy
Volunteer Distribution LLC, Gainesboro, TN
Quality Specialty Products, St. Christopher, St. Kitts