DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

April 23, 2012

<Doctor Name>
<Address 1>
<Address 2>

Re: Purchasing Medications from Foreign or Unlicensed Suppliers Could Result in Serious Harm to Patients; Counterfeit Altuzan Found in U.S.

Dear Dr._____:

On February 10, 2012, the Food and Drug Administration (FDA) notified you of our concerns regarding medications your practice purchased from Quality Specialty Products (QSP) (also known as Montana Health Care Solutions), and distributed through Volunteer Distribution of Gainesboro, Tennessee. On April 3, 2012, FDA alerted healthcare professionals of a counterfeit version of Roche's Altuzan (400mg/16ml) that originated from a foreign source and was purchased by U.S. medical practices.[1]

According to information received by the FDA, your medical practice purchased Altuzan (400mg/16ml) from QSP/Montana Health Care Solutions. QSP's products were distributed through a company called Volunteer Distribution. Packaging or vials that claim to be Roche's Altuzan with lot number B6021 found in the United States should be considered counterfeit. The counterfeit version of Altuzan does not contain any active ingredient. FDA has information that Volunteer Distribution may have distributed the counterfeit version of Altuzan (400 mg/16ml) with lot number B6021.

Regardless of whether counterfeit versions of Altuzan were distributed in the United States, Altuzan itself is *not* approved by FDA. Altuzan is the Turkish brand name for bevacizumab. FDA is very concerned that Altuzan and all products from these suppliers may cause harm to patients, because FDA cannot ensure their safety, efficacy, or quality.

Other drug products obtained from QSP, Montana Health Care Solutions, Volunteer Distribution, or other foreign or unlicensed suppliers may be from unknown sources, may have unknown ingredients, may be counterfeit, or may not have been manufactured, transported or stored under proper conditions, as required by U.S. law, regulations, and standards.

Purchasing prescription drug products, such as cancer medications, from foreign or unlicensed suppliers puts patients at risk of exposure to drugs that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous. In most cases, purchasing unapproved prescription drugs from foreign sources violates the Federal Food, Drug, and Cosmetic Act and is illegal.

FDA requests that you cease using, and retain and secure *all* remaining products, purchased from QSP, Montana Health Care Solutions, Volunteer Distribution, or any other foreign or unlicensed U.S. sources until further notice. Please do not return any product(s) 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(s) at a future date.

[1] http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm298047.htm

On January 13, 2012, FDA issued a notice to health care providers about the risks of purchasing unapproved cancer medications from unlicensed sources.[2] This notice includes information on how to identify whether your distributor is licensed and the product you receive is FDA-approved.

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 at:

  http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/ucm082725.pdf, 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.

You can obtain updates specifically related to this issue from FDA's website at:
http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm

FDA is committed to promoting and protecting the public health by ensuring that only safe, effective, and high-quality drugs 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: Linda K. Whitney, MA, Executive Director, Medical Board of California
Virginia Herold, Executive Officer, California State Board of Pharmacy
Andrew Holt, Pharm.D., Executive Director, Tennessee Board of Pharmacy
Humayun J. Chaudhry, DO, FACP, President, Federation of State Medical Boards
Carmen Catizone, M.S., R.Ph., D.Ph., Executive Director, National Association of Boards of Pharmacy

[2] Notice of Risks of Purchasing Unapproved Injectable Cancer Medications
http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf