DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

June 28, 2012

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

Re: Purchasing Medications from Foreign or Unlicensed Suppliers Could Result in Serious Harm to Patients

Dear Dr._____:

The U.S. Food and Drug Administration ("FDA" or "Agency") has received information indicating that your medical practice purchased multiple medications from a foreign distributor named Clinical Care, Quality Specialty Products (QSP), Montana Healthcare Solutions, or Bridgewater Medical. Most, if not all, of the products sold and distributed by this distributor have not been approved by the FDA and may include counterfeit versions of Avastin or Altuzan. The manufacture and handling of these products may not be of suitable quality to ensure safety or efficacy, and the products have not been proven to be safe and effective pursuant to FDA standards. The Agency is very concerned that products distributed by this distributor may cause harm to patients, because they may be unsafe or ineffective.

FDA has previously posted information about U.S. medical practices which are putting patients' health at risk by purchasing medications from foreign or unlicensed suppliers that sold illegal prescription medications that may have included counterfeit versions of Avastin and Altuzan. (http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm)

Drug products obtained from Clinical Care, QSP, Montana Healthcare Solutions, Bridgewater Medical, 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. Such products put patients at risk of exposure to ineffective or dangerous drugs. In virtually all 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 Clinical Care, QSP, Montana Healthcare Solutions, Bridgewater Medical, 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.

On January 13, 2012, FDA issued a notice to Healthcare providers about the risks of purchasing unapproved injectable cancer medications from unlicensed sources.[1] This notice includes information on how to identify whether your distributor or the product you receive is legitimate.

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.

Healthcare 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.

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 should you have any questions regarding this letter.

Sincerely,

/s/

S. Leigh Verbois, Ph.D.
Acting Deputy Director
Division of Supply Chain Integrity
Office of Drug Security, Integrity, and Recalls
Office of Compliance
Center for Drug Evaluation and Research

cc: <Executive Director, State Board>
Humayun J. Chaudhry, DO, FACP, President, Federation of State Medical Boards

Encl.

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