Letters to Doctors about Risks of Purchasing Unapproved Versions of Botox and Other Medications from Foreign or Unlicensed Suppliers

Statement issued: December 19, 2012
Read text of FDA letter

Read list of Doctor's names

The U.S. Food and Drug Administration (FDA) has alerted more than 350 medical practices that they may have received unapproved medications, including unapproved versions of Botox, from a foreign supplier. These medications may be counterfeit, contaminated, improperly stored and transported, ineffective, and/or unsafe. Medical practices that purchase and administer illegal and unapproved medications from foreign sources are placing patients at risk and potentially depriving them of proper treatment.

To minimize the chance of patients receiving an unapproved, counterfeit, unsafe, or ineffective medication, FDA requests that medical practices stop administering the unapproved versions of Botox and any other products they have received from foreign suppliers owned and operated by Canada Drugs and known under the following names: Quality Specialty Products (QSP), A+ Health Supplies, QP Medical, Bridgewater Medical, or Clinical Care. Many, if not all, of the products sold and distributed by these suppliers have not been approved by FDA. Therefore, FDA cannot confirm that the manufacture and handling of these products follow U.S. regulations or that these medications are safe and effective for their intended uses.

Medications not approved by FDA may also lack the necessary and required labels that ensure their appropriate and safe use. For example, unapproved botulinum toxin products may not contain the boxed warning or Medication Guide required in FDA-approved botulinum products. As a result, health care practitioners and patients may not be fully informed of the potential serious risk of harm or death from the use of these products.

The **text** of the letter FDA sent to the physicians or medical practices on November 30, 2012 is below, along with a **list** of the doctors and clinics to which the letter was sent.

FDA urges the health care community to examine its purchasing practices to make sure that products are purchased directly from the manufacturer or from state-licensed wholesale drug distributors in the United States. Health care professionals, pharmacies, and wholesalers/distributors are valuable partners in efforts to protect consumers from the risks of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. The receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering them.

Report any suspected criminal activity to FDA's **Office of Criminal Investigations (s…/FDAgov/4272)** (OCI) by calling 1-800-551-3989 or visiting the OCI Web Site.

To verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business, use the link or contact information provided for **each respective state (/web/20160808113145/http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.h**

So far in 2012, FDA has issued **letters to medical practices (/web/20160808113145/http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.h** the United States that purchased unapproved medications from foreign suppliers five times: on February 10, April 5, April 23, June 28, and September 10.

Text of FDA Letter:

November 30, 2012

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

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

Dear Dr.:

The U.S. Food and Drug Administration (FDA) has received information indicating that your medical practice has received medications from a foreign supplier owned and operated by Canada Drugs, known as Quality Specialty Products (QSP), A+ Health Supplies, QP Medical, Bridgewater Medical, or Clinical Care. Most, if not all, of the products sold and distributed by these suppliers, including versions of Botox®, have not been approved by FDA. 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. FDA is very concerned that products distributed by these suppliers may cause harm to patients, because they may be unsafe or ineffective.

Medications obtained from Quality Specialty Products (QSP), A+ Health Supplies, QP Medical, Bridgewater Medical, Clinical Care, 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 products. In virtually all cases, importing or causing the importation of unapproved prescription medications from foreign sources violates the Federal Food, Drug, and Cosmetic Act and is illegal. FDA has previously warned about unapproved and counterfeit oncology products obtained from some of these same foreign suppliers.**[1]**

Medications that are not approved by FDA may lack necessary and required labeling to assure their appropriate and safe use. For example, FDA has determined that a prominent “boxed” warning is required in the labeling for medications that have special problems, particularly ones that may lead to death or serious injury. A Medication Guide that contains information that can help patients avoid serious adverse events may be required instead of, or in addition to, a boxed warning. Unapproved botulinum toxin products may not contain the boxed warning or Medication Guide in its labeling as required in FDA-approved products. As a result, the healthcare provider and patient may not be fully informed of the serious risk of harm or death associated with botulinum toxin products.

F[illegible]hat you cease using, and retain and secure *all* remaining products purchased or received from Quality S[illegible]ucts (QSP), A+ Health Supplies, QP Medical, Bridgewater Medical, Clinical Care, 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. If any unapproved medications remain in your possession, please contact FDA's **Office of Criminal Investigations (ssNODELINK/FDAgov/4272)** (OCI) to arrange for the collection of the medications.

On January 13, 2012, FDA issued a notice to Healthcare providers about the risks of purchasing unapproved medications from unlicensed sources, and included information on how to identify whether distributors or the products received are legitimate.**[2]**

Information regarding any criminal activity involving the importation and use of foreign unapproved medications can be reported to FDA's **Office of Criminal Investigations (ssNODELINK/FDAgov/4272)** (OCI).

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

· **Complete and submit the report online (/web/20160808113145/https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.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, effective, and high-quality medications are available to the American public. Please contact
Eleni Anagnostiadis at DrugSupplyChainIntegrity@fda.hhs.gov should you have any questions regarding this letter.

Sincerely,

/S /

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

cc: <Name @ State>, State Board of Medical Examiners
Humayun J. Chaudhry, DO, FACP, President, Federation of State Medical Boards

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[1] **Another counterfeit cancer medicine found in U.S. - Illegal practice puts patients at risk (/web/20160808113145/http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm298047.h**

[2] **Notice of Risks of Purchasing Unapproved Injectable Cancer Medications (/web/20160808113145/http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/U**
