DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

July 11, 2013

<Doctor/Practice Name>
<Address 1>
<Address 2>

Alert: Suspect Versions of Botox Distributed by "Online Botox Pharmacy," "Onlinebotox.com," and "Onlinebotox."

Dear Dr.:

We are writing to alert you to a potential public health issue with certain products labeled as "Botox," that have been distributed in the United States by a company that goes by the names "Online Botox Pharmacy," "Onlinebotox.com," and "Onlinebotox."[1] The U.S. Food and Drug Administration (FDA) has received information indicating that your medical practice may have received such products from this company. FDA is very concerned that this product, and others distributed by this company, may cause harm to patients because they may be unsafe or ineffective.

Prescription drugs distributed by the above company may be counterfeit (not manufactured or distributed by the company indicated on their label) and/or may be drugs from foreign or unknown sources that are not approved for distribution in the United States. These products may have unknown or harmful ingredients, and may not have been manufactured, transported or stored under proper conditions as required by U.S. law and regulations.

In particular, FDA has confirmed that this company has sold product labeled as "Botox" which does not meet legal requirements for sale in the U.S. and may pose a public health risk. This product has not undergone FDA scientific and regulatory review to establish safety, efficacy or therapeutic equivalence to any U.S. approved product. There is no verification of its ingredients, manufacture, or handling.

Specifically, this company has distributed product consisting of a vial labeled as a foreign version of "Botox" not approved by the FDA for sale in the U.S., packaged in an outer carton which is not the original one supplied by the manufacturer of legally-marketed Botox.[2] On such products distributed by this company:

- the outer carton displays the active ingredient as "Botulinum Toxin Type A"; and/or
- the lot numbers and expiration dates on the outer carton and accompanying vial do not match. For example, FDA has identified the following:

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[1]Based on our investigation to date, this company does not currently hold a valid license as either a wholesale distributor of prescription drugs or as a pharmacy, as required by law.

[2] For FDA's initial public notification about these products, see Fraudulent Versions of Botox Found in the United States http://www.fda.gov/Drugs/DrugSafety/ucm349503.htm

Example 1

Lot #	Exp Date
C3016 C3 (carton)	10-2014
C3121 C3 (vial)	04-2015

Example 2

Lot #	Exp Date
C3060 C3 (carton)	01-2015
C3121 C3 (vial)	04-2015

Products with any of these lot numbers and expiration dates, labeled as "Botox," from this company, should be considered suspect.

By contrast, FDA-approved Botox for injection (100 units/vial), manufactured by Allergan, displays the active ingredient as "OnabotulinumtoxinA" on the outer carton and vial. Also, on the U.S.-approved Allergan product, both the outer (carton) and inner (vial) labels bear the same lot number and same expiration date. Currently, FDA's concerns, as described in this letter, do not apply to Allergan's FDA-approved Botox product.

If you currently have *any* medical products distributed by "Online Botox Pharmacy," "Onlinebotox.com," or "Onlinebotox," FDA requests that you cease using, and retain and secure all remaining units of those products. Please do not return any product(s) to the place of purchase at this time. FDA is continuing to investigate this situation. Please contact FDA, through the Office of Criminal Investigations (OCI) at 1-800-551-3989 to arrange for the potential examination and collection of the products.

General Recommendations

To help avoid receiving prescription drugs that do not comply with U.S. regulatory requirements, which can help both to protect the public health and to reduce potential legal liability,[3] FDA recommends that health care providers and their staff:

- Be cautious when considering solicitations from unknown distributors who advertise via email or fax blasts.

- Check to see if the distributor holds a current state license before placing an order. (Links to each state's licensing authorities are provided here: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm)

[3]Under federal law, it is illegal to import, or to cause the importation of, drugs that do not comply with U.S. law, including FDA approval and labeling requirements. This law applies not only to manufacturers and distributors, but also to purchasers of such products. Parties who purchase such non-compliant drugs could face personal liability, including the possibility of criminal sanctions.

    - Wholesale distributors are required to be licensed in the state(s) in which they do business, although licensure alone is not a guarantee of compliance with all legal requirements.

- Be wary if the price of a medicine sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, substandard, or unapproved.
- Carefully inspect all product and packaging. Look for these signs, which may indicate that the product is not FDA-approved or otherwise does not meet U.S. regulatory requirements:
    - The medicine has a different brand name than what was ordered.
    - The packaging or label looks different from the product you usually receive.
    - Portions, or all, of the labeling are not in English.
    - Shipping addresses, postmarks, or other materials indicate that the package came from outside of the U.S.
    - The labeling does not state "Rx only" even though the product is restricted to prescription use in the U.S.
    - The dosing recommendations are unfamiliar.
    - The dosage form or route of administration is different (e.g., ampule instead of pre-filled syringe).
    - The product does not display a National Drug Code (NDC) number.[4]
    - The lot numbers and expiration dates on the carton do not match those on labels of the containers included in the carton.
    - The drug was not shipped under conditions that satisfy labeled storage requirements. For example, if the drug is labeled to require refrigeration, it was not shipped with cold packs or other measures to ensure temperature control.

Health care providers and patients are encouraged to report any suspicious medical products to FDA's Office of Criminal Investigations (OCI), www.fda.gov/oci. In addition, health care providers and patients are encouraged to report any adverse events, including adverse events involving 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. Health 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

[4] Inclusion of an NDC number on the label is not required, nor does it denote FDA approval of the product. However, the absence of an NDC on the label may suggest that the product was not originally manufactured for the U.S. market, and that in turn may suggest that it may not comply with U.S. requirements.

- 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 helping to ensure that only safe, effective, and high-quality medications are available to the American public. Please contact FDA DrugSupplyChainIntegrity@fda.hhs.gov should you have any questions regarding this letter.

Sincerely,

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

cc: <Name @ State>
<Name @ National Organization>