DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

March 30, 2016

Peter N. Bogdan, MD
New Horizons Medical Spa
3505 Hill Blvd., Suite H
Yorktown, NY 10598

**ALERT: Your Practice Purchased Unapproved Drugs or Devices Distributed by TC Medical, also known as SB Medical**

Dear Dr. Bogdan:

The U.S. Food and Drug Administration (FDA) has information indicating your medical practice purchased unapproved prescription drug(s) and/or injectable devices from an unlicensed supplier, TC Medical (also known as SB Medical; hereinafter referred to as TC Medical). FDA previously sent you two other letters regarding unapproved prescription drug(s) and/or unapproved/uncleared injectable devices that you received from other distributors as well: Gallant Pharma International, Inc., and Botox Online Pharmacy. Administering such products puts your patients at risk.

Prescription drugs and/or injectable devices (products) distributed by TC Medical may be counterfeit (not manufactured or distributed by the company indicated on the label) and/or may be from foreign or unknown sources and are not approved for distribution in the United States. These products may have unknown ingredients, or may not have been manufactured, transported, or stored under proper conditions as required by U.S. law, regulations, and standards. Such products are considered misbranded and/or adulterated under the Federal Food, Drug and Cosmetic Act (FD&C Act).

In particular, counterfeit Botox, distributed by TC Medical, was found in the United States and may have been sold to doctors' offices and medical clinics nationwide. Both the outer carton and vial associated with the product are counterfeit. The counterfeit product can be identified by one or more of the following: the vial is missing the lot number, the outer carton does not have any entries next to "LOT:", "MFG:", "EXP:", and/or the outer carton and vial display the active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." [1]

Medical practices should stop using any remaining product purchased from TC Medical. The last known purchases of TC Medical's products were made in 2014, but it is not known whether any of these drugs and devices are still in distribution. The chart below lists unapproved drugs and devices sold by TC Medical; however, this list is not all-inclusive. Please contact FDA, through the Office of Criminal Investigations (OCI) at 1-800-551-3989, if you have questions about TC Medical, or the drugs or devices they distributed.

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|---|---|---|---|---|
| Aclasta | Actemra | Artzal | Bonviva | Botox |
| Botox Cosmetic | Dysport | Euflexxa | Hyalgan | Juvederm |
| Lucentis | Mabthera | Macrolane | Orencia | Orthovisc |
| Prolia | Radiesse | Remicade | Restylane | Supartz |
| Synvisc | Zometa | | | |

[1] Counterfeit Version of Botox Found in the United States: http://www.fda.gov/Drugs/DrugSafety/ucm443217.htm

***Combating the Illegal Distribution of Unapproved Products to U.S. Medical Practices***

In recent years, distributors who violated federal law, such as TC Medical, have targeted clinical medical settings for the sale of foreign and unapproved drugs and devices. Medical offices are often contacted through mass advertising campaigns via "blast faxes," phone calls, direct email, and online marketing. These distributors often pursue clinics and hospitals in order to market physician-administered products, including a variety of injectable drugs and devices.

In addition to putting patients at risk, receiving misbranded or adulterated drugs and devices in interstate commerce and delivering or offering to deliver those drugs and devices to (or for use on) others violates federal law. FDA takes this threat to public safety seriously and has worked with the U.S. Department of Justice to hold numerous parties civilly and criminally accountable. SB Medical, Inc. and TC Medical Group were fined $45 million and required to forfeit an additional $30 million for orchestrating a multi-year conspiracy to smuggle misbranded prescription pharmaceuticals and unapproved devices into the United States.

Beginning January 01, 2015, the Drug Supply Chain Security Act (21 U.S.C. 352 et seq.) requires all healthcare providers who dispense or administer prescription drugs to patients to purchase their prescription drug products only from authorized trading partners licensed by and/or registered with the state or Federal government, as applicable.[2] This helps minimize patient exposure to potentially dangerous and illegal drug products and helps prevent them from being harmed.

FDA is committed to promoting and protecting public health by helping ensure only safe, effective, and high-quality drugs and devices are available to the American public. Health care providers and patients are encouraged to report any suspicious medical products to FDA's Office of Criminal Investigations www.fda.gov/oci.

Please see the attachment to this letter, entitled: *Tips to Help Health Care Providers Safely Purchase Drugs and Devices From Pharmaceutical and Medical Device Distributors.* Additional information about how to safely purchase medicines can be found on the FDA website at www.fda.gov/knowyoursource. Feel free to contact DrugSupplyChainIntegrity@fda.hhs.gov should you have any questions regarding this letter.

Sincerely,

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

Keisha R. Thomas
Acting Director
Division of Premarket and Labeling Compliance
Office of Compliance
Center for Devices and Radiological Health

cc: Stephen J. Boese, Executive Secretary, New York State Board of Medicine

[2] Section 581(2) of the FD&C Act defines the term "authorized" as it relates to wholesale distributors, manufacturers, repackagers, and dispensers. You are responsible for assuring that your immediate trading partners are "authorized" within the meaning of this provision.

# ATTACHMENT

## *Tips to Help Health Care Providers Safely Purchase Drugs and Devices from Pharmaceutical and Medical Device Distributors*

Health care providers can help protect the public health and reduce potential legal liability by avoiding purchasing prescription drugs and devices that do not comply with U.S. regulatory requirements. To help ensure safe drug and device purchasing from medical product distributors, FDA recommends health care providers and their staff:

- **Ensure you receive** FDA-approved prescription drugs and FDA-approved or cleared devices-- those products not FDA-approved or cleared may have unknown or harmful ingredients, or may not have been manufactured, transported, or stored under proper conditions.

- Buying directly from the manufacturer or a wholesale drug distributor licensed in your state will reduce the chances of unsafe or ineffective drugs or devices reaching your patients. You can also check Drugs@FDA http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm and Devices@FDA http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm to find out whether a product is FDA-approved/cleared.

- **Beware of offers too good to be true** – Aggressive marketing tactics and deep discounts on prescription products (drugs and devices) may indicate that the products are stolen, counterfeit, substandard, or unapproved/uncleared. Be cautious when considering solicitations from unknown distributors who advertise via email or fax blasts.

- **Buy only from state-licensed wholesale drug distributors** – While licensure alone is not a guarantee, looking for valid licensure in your state will reduce the chances of unsafe and ineffective drugs reaching your patients. To verify a wholesale drug distributor's license in the state(s) where it is conducting business, use the link provided to access your state licensing authority's database or contact information http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm

- **Caution** – Check for these signs that a prescription product (drug or device) may be unsafe, ineffective, or fake:
  - The labeling is not in English;
  - The packaging looks slightly different from the FDA-approved or cleared product;
  - The product name differs from the name of the FDA-approved or cleared product;
  - The dosing recommendations are unfamiliar;
  - The labeling does not state "Rx only" (for a drug) and "Caution: Federal law restricts this device to sale by or on the order of a physician [or other authorized medical practitioner]" (for a device) even though the product is restricted to prescription use in the U.S;
  - A National Drug Code (NDC) number does not appear on the label or labeling of a prescription drug product;[1]
  - The product (drug or device) was not shipped under conditions that satisfy labeled storage requirements. For example, the drug is labeled to require refrigeration, but was not shipped with cold packs or other means of ensuring temperature control;
  - Safety information or warnings are missing; and/or
  - The dosage form or administration is different than what you typically see (i.e., tablet vs. capsule).

- **Pay close attention to patient feedback –** If several patients report that they are experiencing a new side effect or a lack of therapeutic effect from the same product, consider that the drug may be substandard or counterfeit. 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
  - 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.

[1] 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.