DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

<Date>

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

ALERT: Your Practice May Have Purchased Unapproved/Uncleared Drugs or Devices Distributed by Gallant Pharma

Dear Dr. _____:

The U.S. Food and Drug Administration (FDA) has information indicating that your medical practice may have purchased unapproved prescription drug(s) or unapproved/uncleared injectable devices distributed by Gallant Pharma International, Inc., also known as Gallant Medical International, Inc. ("Gallant"). Administering such products, which are virtually always also misbranded and/or adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act), puts your patients at risk. Drugs or devices that have not undergone scientific and regulatory review by FDA to ensure their safety and efficacy may have unknown ingredients, improper labeling, or may not have been manufactured, transported or stored under proper conditions. 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 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. Gallant and twelve individuals, including a doctor and an office manager, have been convicted for their roles in distributing drugs and devices that have not been approved or cleared by FDA in the U.S. The unapproved drugs and unapproved/uncleared devices sold by Gallant were obtained from foreign sources and shipped and stored outside of the regulated supply chain.

The last known purchases of Gallant's products were made in 2013, but it is not known whether any of these drugs and devices are still in distribution. The chart below is a list of unapproved chemotherapy and injectable cosmetic drugs and devices sold by Gallant; however, it is not meant to be all-inclusive. Please contact FDA, through the Office of Criminal Investigations (OCI) at 1-800-551-3989, if you have questions about Gallant, or the drugs they distributed.

- Aclasta
- Alimta
- Anzemet
- Avastin
- Botox
- Dysport
- Eloxatin
- Erbitux
- Euflexxa
- Faslodex
- Gemzar
- Herceptin
- Herclon
- Hyalgan
- Hydrocortistab
- Juvederm Ultra 2
- Juvederm Ultra 3
- Juvederm Ultra 4
- Methylprednisone
- Neulasta
- Neupogen
- Orencia
- Perlane
- Perlane-L
- Radiesse
- Remicade
- Restylane
- Restylane-L
- Ristova
- Rituxan
- Sculptra
- Supartz
- Synvisc 3
- Synvisc One
- Taxotere
- Triamcinalone
- Velcade
- Xeomin
- Zometa

Illegal Distribution of Unapproved Drug Products to U.S. Medical Practices

In recent years, distributors who have violated federal law, such as Gallant, have targeted clinical settings for the sale of foreign and unapproved drugs. 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 for sale of physician-administered drugs, including a variety of injectable drugs.

Under the Drug Supply Chain Security Act (21 U.S.C. 351 et seq.), as of January 1, 2015, all healthcare providers who dispense or administer prescription drugs to patients will be required to purchase their prescription drug products only from authorized trading partners licensed by or registered with the state or Federal government, as applicable.[1] This will help minimize the exposure to patients and protect patients from being harmed by potentially dangerous and illegal drug products.

FDA is committed to promoting and protecting the public health by helping to ensure that 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 From Pharmaceutical 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,

/s/

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

/s/

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

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

[1] 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 From Pharmaceutical Distributors

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

- **Ensure you receive** FDA-approved prescription drugs – Drugs that are not FDA-approved 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 reaching your patients.

- **Beware of offers too good to be true** – Aggressive marketing tactics and deep discounts on prescription drugs may indicate that the products are stolen, counterfeit, substandard, or unapproved.

- **Buy only from state- licensed wholesale drug distributors** – While licensure alone is not a guarantee, looking for valid licensure in your state will help reduce the chances of unsafe and ineffective drugs reaching your patients.

- **Caution** – Check for these signs that a prescription drug may be unsafe, ineffective, or fake:
  - The label is not in English;
  - The packaging looks slightly different from the FDA-approved product;
  - The product name differs from the name of the FDA-approved drug;
  - The dosing recommendations are unfamiliar;
  - Safety information or warnings are missing; and/or
  - The dosage form or administration is different.

- **Pay close attention to patient feedback** – If several patients report that they are experiencing a new side effect or 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/AboutFDA/AboutThisWebsite/WebsitePolicies/ViewingFiles/default.htm, 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.