



May 13, 2013

Alert: Suspect Prescription Drugs Distributed by Medical Device King

Dear Licensee:

We are writing to alert you to a potential public health problem with certain prescription drugs. The U.S. Food and Drug Administration (FDA) has received information indicating that your medical practice may have received prescription drug(s) distributed by Medical Device King (MDK), a distributor that is not licensed in any state. FDA is very concerned these products may cause harm to patients, because they may be unsafe or ineffective.

Prescription drugs distributed by MDK may be counterfeit drugs (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 drugs 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.

In particular, counterfeit units of product labeled as Roche's "Altuzan (bevacizumab) concentrate for solution for infusion," and distributed by MDK, have been discovered in the United States. Units of this product labeled as "Altuzan (bevacizumab) 400 mg/16 MI," with the lot numbers B6022B01 or B6024B01, are particularly suspect. FDA lab tests have confirmed that at least one batch of such product distributed in the U.S. contains no active ingredient.¹

In addition to drugs labeled with the trade (brand) name Altuzan, MDK has distributed drugs labeled with the trade names Aclasta and MabThera. No drugs with these three trade names are approved for use in the United States. This is of great concern because these drugs have not undergone scientific and regulatory review by FDA to ensure their safety and efficacy. While these drugs purport to have the same active ingredients as other drug products that have U.S. market approval, they are not legally marketed and have not been established by FDA to be therapeutically equivalent to or interchangeable with U.S. approved products that contain the same active ingredients.

In addition, MDK may have provided versions of other drugs, including those labeled with the following trade names, which do not comply with U.S. regulatory requirements:

¹ Health Care Provider Alert: Another Counterfeit Cancer Medicine Found in United States:
<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/ucm338283.htm>

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|-----------|----------|------------|----------|--------------|-----------------|
| Abraxane | Alimta | Aloxi | Aredia | Avastin | Boniva |
| Botox | Doxil | Dysport | Eloxatin | Faslodex | Gemzar |
| Herceptin | Implanon | Leucovorin | Menopur | Methotrexate | Mirena |
| Neulasta | Neupogen | Prolia | Propofol | Rituxan | Sandostatin-Lar |
| Taxotere | Velcade | Venofer | Vidaza | Xeomin | Xolair |
| Zometa | | | | | |

The preceding list is not meant to be an all-inclusive list of products distributed by MDK.

If you currently have any medical products distributed by MDK, 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 evaluate 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 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,² 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>)
 - 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.

²Under 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.

- 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.
 - The labeling does not state "Rx only" even though the product is restricted to prescription use in the U.S.
 - Shipping addresses, postmarks, or other materials indicate that the package came from outside of 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.³
 - 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
- 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.

³ 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.

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 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