Clifton Health Department
Food Recall Notification

Public Health
Prevent. Promote. Protect.

Food/Drug/Pet Recall: AmEx Pharmacy

AmEx Pharmacy is voluntarily recalling one Lot of Bevacizumab 1.25mg/0.05mL 31G Injectable to the consumer/user level. The Monoject Syringe of this product may become difficult to express, and when additional force is applied, while the needle is in the eye, may cause injury to the patient.

The additional force needed to express the drug product could potentially result in damage to the eye while the needle is in the eye. To date, AmEx Pharmacy has received three reports associated with the Lot being recalled as either being difficult to express, two of which, resulted in an Adverse Drug Event.

The product is used for Wet Age-related Macular Degeneration and Diabetic Retinopathy. It is individually wrapped and labeled in a Tyvek pouch which is then placed in a labeled amber bag to protect from light. The affected Lot ofBevacizumab 1.25mg/0.05m 3 lG Injectable is 190212AB, BUD 5/13/2019. The product can be identified by referencing the Lot number 190212AB, which prominently appears on all labeling. This specific Lot was distributed nationwide to ophthalmologist clinics in the following states: PA, IL, TX, WI, KS, TN, IN, & AZ.

AmEx Pharmacy is notifying its consignees by telephone and overnight mail and is arranging for return/replacement of all recalled product. Administering physicians that have product which is being recalled should stop use, remove from inventory and return to AmEx Pharmacy.

Consumers with questions regarding this recall can contact AmEx Pharmacy at (800) 644 - 9431 or by email at pharmacist@amexpharmacy.com during normal business hours Monday through Friday 9:00a.m. - 6:00p.m, EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to being administered this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

. Complete and submit the report Online: www.fda.gov/medwatch/report.htm
. Regular Mail or Fax: 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

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No action is required of local health departments at this time for any of these recalls. If any

requests for assistance are received from FDA, the Public Health and Food Protection Program will contact you. For additional information regarding warnings and recalls, please click on the weblink below.

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For all recalls - http://www.recalls.gov/recent.html