

September 27, 2010

Amgen Initiates Voluntary Nationwide Recall of Certain Lots of EPOGEN® and PROCRIT®



Amgen announced September 24, 2010 that certain lots of EPOGEN(R) and PROCRIT(R) (Epoetin alfa) vials are being voluntarily recalled from specialty distributors, wholesalers, pharmacies and healthcare providers as a precaution. The product that is being recalled may contain extremely thin glass flakes (lamellae) that are barely visible in most cases. The lamellae result from the interaction of the formulation with glass vials over the shelf life of the product. The recall is being conducted in cooperation with the United States Food and Drug Administration.

Evaluations by Amgen and Centocor Ortho Biotech Products, L.P. found a low potential to impact patients who may have received the affected product. The potential serious adverse events resulting from the use of a sterile injectable product with particulates by the intravenous route include embolic, thrombotic and other vascular events (e.g., phlebitis), and by the subcutaneous route include foreign body granuloma, local injection site reactions, and increased immunogenicity.

Adverse events related to EPOGEN should be reported to 1-800-77-AMGEN. Adverse events related to PROCRIT should be reported to 1-800-547-6446. Consumers with questions regarding this recall can contact Amgen at 1-800-77-AMGEN (open 24 hours per day, 7 days per week) or Centocor Ortho Biotech Products at 1-800-547-6446 (open 24 hours per day, 7 days per week).

The affected product lot numbers and expiration dates are available at <http://www.epogen.com/professional/pdf/epogen-consignee-notification-letter.pdf> and http://www.procrit.com/sites/default/files/pdf/Supplier_Procrit_Recall_Letter.pdf.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Adverse events that may be related to the use of this product may also be reported to the United States Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm.
- Mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

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