



Amgen
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
805. 447.1000

24 September 2010

Dear Health Care Professional:

Amgen Inc. and Centocor Ortho Biotech Products, L.P. have voluntarily recalled EPOGEN®/ PROCRIT® (epoetin alfa) vials that failed to meet a quality requirement. This action is being taken as a safety precaution in coordination with the FDA. Any EPOGEN® lots which may contain barely visible glass flakes (lamellae) are being recalled, and only those lots passing quality standards will remain available.

This recall is intended as a precautionary measure to minimize the likelihood of any patient being exposed to lamellae, especially for children with chemotherapy induced anemia in whom intravenous administration has been recommended. 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. The seriousness of the risks would appear to be greater with intravenous administration compared to when the drug is given by the subcutaneous route. As noted in the package insert, parenteral drug products should be carefully inspected visually for particulate matter and discoloration prior to administration. Do not use any EPOGEN® vials exhibiting particulate matter or discoloration. Additional vials, when available, will be provided to replace any recalled product.

EPOGEN®, PROCRIT® are manufactured by Amgen Inc. During manual visual inspection of EPOGEN® / PROCRIT® vials, a portion of vials were found to contain barely visible glass flakes (lamellae). The lamellae appear to come from the inner surface of the vials and arise over time from interactions of the product with the vials. The lamellae are different from typical glass particles due to glass (e.g. vial) breakage. They are thin (approximately 1 micron), flexible and can be up to 1 mm in length.

To date, no trends have been identified in complaints or adverse event reporting that are directly attributable to glass lamellae from any lot of EPOGEN®, however, the ability to identify possible increases in adverse drug reactions is significantly limited due to the nature of adverse event reporting.

Both companies will continue to monitor for reports of adverse drug reactions and product complaints.

We appreciate your immediate attention and cooperation in this matter. For specific questions on recall logistics contact Vince Ayala from Amgen at 1-805-447-3557. For clinical questions, or wish to report adverse patient experiences please contact Amgen

Medical Information at 1-800-77-AMGEN (1-800-772-6436). Please provide the lot number in your contact.

Alternatively, adverse events may be reported to FDA's MedWatch reporting system

- by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178),
- online (<https://www.accessdata.fda.gov/scripts/medwatch/>) or
- mailed, using the MedWatch for FDA 3500 postage paid form, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787

Sincerely,

A handwritten signature in blue ink that reads "Sean Harper MD". The signature is written in a cursive style with a large "S" and "H".

Sean Harper, M.D.
Senior Vice President Global Development and Chief Medical Officer
Amgen