



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

September 22, 2010

Re: **EPOGEN<sup>®</sup> (Epoetin alfa) Voluntary Recall**

Dear Customer:

Amgen is conducting a voluntary recall of certain lots of EPOGEN<sup>®</sup> (Epoetin alfa) due to the presence of extremely thin glass flakes (lamellae), which are very difficult to see, discovered in a number of EPOGEN<sup>®</sup> vials.

With patient safety as our top priority, this voluntary recall is being initiated as a precautionary measure and in coordination with the Food and Drug Administration. Intravenous (IV) administration could have potentially serious adverse events resulting from the use of a sterile injectable product with particulates which could include embolic, thrombotic and other vascular events (e.g. phlebitis). Risks of injecting particulates by the subcutaneous route could include foreign body granuloma, local injection site reactions, and increased immunogenicity. Do not use any EPOGEN<sup>®</sup> vials exhibiting particulate matter or discoloration (see EPOGEN<sup>®</sup> USPI under PREPARATION AND ADMINISTRATION OF EPOGEN<sup>®</sup>). In patients on hemodialysis, the IV route is recommended (see EPOGEN<sup>®</sup> USPI under WARNINGS: Pure Red Cell Aplasia).

We appreciate your immediate attention and cooperation in this matter and your assistance in disseminating this information among the healthcare providers in your facilities. 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(s) 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
- by mail, using the MedWatch for FDA 3500 postage paid form, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787

Please see the accompanying EPOGEN<sup>®</sup> full prescribing information, including **Boxed WARNINGS** and Medication Guide.

Sincerely,

Sean Harper, M.D.

Senior Vice President Global Development and Chief Medical Officer  
Amgen