NATIONAL PBM COMMUNICATION
AMGEN ANNOUNCES NATIONWIDE VOLUNTARY RECALL OF EPOGEN® (EPOETIN ALFA) LOT NUMBERS P118857 and P123055
August 28, 2008

Amgen is announcing that it is voluntarily recalling two lots (P118857 and P123055) of EPOGEN® (Epoetin alfa) after having identified cracks in the necks of a small number of vials upon post-manufacturing inspection. No other lot of this product is affected by this recall.

EPOGEN® (Epoetin alfa) is used in the management of patients with anemia. The following EPOGEN® (Epoetin alfa) products carry the affected lot number:

NDC	Description	Lot Number	Expiration Date
55513-267-01	Individual single use vials of EPOGEN® (Epoetin alfa) 3000 Units/1 mL	P118857	12/31/2010
55513-267-10	Cartons containing 10 single use vials of EPOGEN® (Epoetin alfa) 3000 Units/1 mL	P118857	12/31/2010
55513-148-01	Individual single use vials of EPOGEN® (Epoetin alfa) 4000 Units/1 mL	P123055	1/31/2011
55513-148-10	Cartons containing 10 single use vials of EPOGEN® (Epoetin alfa) 4000 Units/1 mL	P123055	1/31/2011

Vials exhibiting even slight cracks may not maintain their sterile condition and should not be used for subcutaneous or intravenous injection.

VA MEDSAFE RECOMMENDATIONS *reinforce those of the manufacturer and include*:

- **Determine whether the affected lot numbers of EPOGEN® (Epoetin alfa) (NDC numbers 55513-267-01, 55513-267-10, Lot P118857, Expiration 12/31/2010 and NDC numbers 55513-148-01, 55513-148-10, Lot P123055, Expiration 1/31/2011) were dispensed to the patient and if so, identify the patients who may have received the affected product and determine the most appropriate method of notifying the patient (a phone call is the first choice; if unable to reach by phone, use/modify accompanying patient letter) with instructions on how to return the affected product and receive a new prescription.**
- **Patients should be advised to contact their Healthcare Provider if they have received and are in possession of EPOGEN® (Epoetin alfa) (NDC numbers 55513-267-01, 55513-267-10, Lot P118857, Expiration 12/31/2010 and NDC numbers 55513-148-01, 55513-148-10, Lot P123055, Expiration 1/31/2011).**
- **Check all floor stock, and all remaining product with the affected lot number at the facility/CMOP level should be returned to McKesson.**
- **Within 5 business days, the Chiefs of Pharmacy are requested to report and confirm to their VISN Formulary Leader or designee that all appropriate patients have been notified, the method notified (e.g. phone call, letter), and date each method was completed.**
- **VISN Formulary Leaders (or designee) will then report back this information to the National PBM via the Feedback tool:**

http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx. **PBM will summarize results and forward to10N (DUSHOM).**

- **CMOP and EPS should also respond to the Feedback Tool above.**
- **Further information regarding the affected lots of EPOGEN® (Epoetin alfa) can be found below.**

URGENT: DRUG RECALL

AMGEN

August 21, 2008
Event 1901

PRODUCT	Product: Epogen® **Lot Number** — **Product Description** — **NDC Number** P118857 — Epogen® 3000 Units/1 mL 10 Vials — 55513-267-10 Epogen® 3000 Units/1 mL Single Use Vial — 55513-267-01 Expiration Date: 12/31/2010 P123055 — Epogen® 4000 Units/1 mL 10 Vials — 55513-148-10 Epogen® 4000 Units/1 mL Single Use Vial — 55513-148-01 Expiration Date: 1/31/2011
REASON	Amgen is conducting a voluntary recall of these lots due to potential cracks in the glass vials. This recall is being conducted to the wholesale level and in coordination with the Food and Drug Administration. Lot No. P118857 was shipped from Amgen between July 16 and July 30, 2008 and Lot No. P123055 was shipped between April 8 and August 18, 2008.
ACTION	Immediately notify your customers of this recall per your internal procedures. 1. Please carry out a physical count and record this data on the Business Reply Form, which is included with this letter. 2. If you still have any of the above lots in your possession, do not release for further distribution and return the lots to the address below. 3. Fax the Business Reply Form to 1-888-258-6247 even if you do not have the referenced product. 4. Return the referenced product and the completed Packing Slip using the prepaid UPS *Return Service*℠ shipping labels to: Stericycle Attn: Recall Coordinator 2670 Executive Dr. Ste A Indianapolis, IN 46241
OTHER INFORMATION	This recall is being carried out to Epogen® wholesale customers solely for the lots referenced above. No other lots, packages, or formulations are within the scope of this recall. For questions, contact Stericycle at 1-888-603-8992. Credit will be issued to the Epogen® wholesale customer at the current wholesale price at the time of this notification. This is applicable for the recalled lots only. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

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