

NEWS



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ORTHO BIOTECH ANNOUNCES NATIONWIDE VOLUNTARY RECALL OF PROCRIT® (EPOETIN ALFA) LOT NUMBER P114942A

BRIDGEWATER, NJ (August 5, 2008) – Ortho Biotech is announcing that it is voluntarily recalling one manufacturing lot (P114942A) of PROCRIT® (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. Approximately 44,292 vials of lot P114942A in the following packaging configurations were distributed between April 15, 2008 and July 17, 2008.

NDC	Description	Lot Number	Expiration Date
59676-312-00	Individual multi-dose vials of PROCRIT® (Epoetin alfa) 10,000 U/2mL	P114942A	12/10
59676-312-04	Cartons containing 4 multi-dose vials of PROCRIT® (Epoetin alfa) 10,000 U/2mL	P114942A	12/10

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

To ensure patient safety, Ortho Biotech is voluntarily recalling PROCRIT vials from this manufacturing lot only. Ortho Biotech is notifying the authorized distributors, prescribing

physicians and patients of this recall. The recall is being conducted in cooperation with the U.S. Food and Drug Administration.

PROCRIT from manufacturing lots other than the above, shipped from an authorized distributor is not being recalled.

PROCRIT vials from the above recalled lot should be promptly returned by contacting the returned goods service provider, at (800) 668-4391.

Healthcare providers and patients with questions about this recall notice can contact the Ortho Biotech Medical Information Department at (888) 227-5624, Monday through Friday, 8:30 am to 5:00 pm EDT.

The amount of PROCRIT being withdrawn represents a very small proportion of the total product within the distribution channel; therefore the company does not anticipate a disruption in product availability for patients.

About Ortho Biotech, L.P.

Ortho Biotech Products, L.P. is a leading biopharmaceutical company devoted to helping improve the lives of patients with cancer and with anemia due to multiple causes, including chronic kidney disease. Since it was founded in 1990, Ortho Biotech and its worldwide affiliates have earned a global reputation for researching, manufacturing and marketing innovative products that enhance patients' health. Located in Bridgewater, N.J., Ortho Biotech is an established market leader in Epoetin alfa therapy for anemia management. The company also markets treatments for recurrent ovarian cancer, rejection of transplanted organs and other serious illnesses. For more information, visit www.orthobiotech.com

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