

## IMPORTANT DRUG WARNING COUNTERFEITING OF PROCRIT®

June 6, 2002

Dear Healthcare Professional:

Ortho Biotech Products, L.P. (OBPLP) recently became aware of the existence of counterfeit drug product labeled as PROCRIT®(epoetin alfa)\* 40,000 U/mL vials in four-pack boxes, **lot number P002641** and expiration **September 2003**. OBPLP is informing physicians, pharmacies, and wholesalers/distributors about this potentially serious health risk. PROCRIT is used primarily for the treatment of anemia associated with chemotherapy, chronic renal failure (pre-dialysis), zidovudine treatment in HIV patients, and patients undergoing elective, noncardiac, nonvascular surgery.

**Based upon the evidence we have reviewed to date, we have determined that these vials are indeed counterfeit. Analysis shows that they contain a clear liquid with active ingredient. The examined vials appear to be intact. However, the concentration of active ingredient is approximately 20 times lower than expected for PROCRIT 40,000 U/mL vials. Based upon evidence available to date, it appears that counterfeiters may be acquiring PROCRIT 2,000 U/mL vials and relabeling the product with counterfeit 40,000 U/mL labels. Because of the lower than labeled strength of the counterfeit vials, it is possible that patients could be under-dosed. In addition, other potential health risks cannot be ruled out at this time.**

Authentic PROCRIT, lot number P002641, expiration September 2003 was last shipped from the OBPLP Distribution Center on February 20, 2002. Based on historical usage patterns and inventory practices, it is likely that virtually all authentic PROCRIT with lot number P002641, already has been used. Thus, any product bearing this lot number in particular, should be considered suspect and be closely examined.

Physicians, pharmacists, nurses and all other healthcare professionals should carefully examine all PROCRIT vials before use. The following information may help in determining if the product you have is counterfeit.

This counterfeit product deviates from authentic PROCRIT in that the counterfeit product may:

- Have a visible "strike-through" on number 6 in the lot number on the vial.
- Have text alignment on the bottom of the folding carton (box) that is shifted to the extreme right side of the panel.
- Have a varnished (shine/gloss) fluted tray, which holds the vials in place. The authentic product has an unvarnished fluted tray that has no shine/gloss.

In order to view pictures illustrating these differences, please log onto [www.procrit.com](http://www.procrit.com) or [www.orthobiotech.com](http://www.orthobiotech.com).

Features of Authentic PROCRIT	Features of this Counterfeit Product
<b>VIAL:</b> No "strike-through" on number "6" as it appears in the lot number. Photo #1	<b>VIAL:</b> "Strike through" on number "6" as it appears in the lot number. Photo #2
<b>FOLDING CARTON (BOX):</b> Text alignment on bottom of folding carton appears with a right hand margin between end of text and edge of carton. Photo #3	<b>FOLDING CARTON (BOX):</b> Text alignment on bottom of folding carton may be shifted to extreme right side of panel without a right hand margin. Photo #3

Please convey this information to your staff and any others who administer PROCRTIT so that they will be able to identify the characteristics of a suspect counterfeit vial.

If you receive any product that you suspect is counterfeit, do not use the product. Please quarantine and store the product under labeled conditions. Promptly contact the FDA at 1 (800) 835-4709, prompt #5 for further instructions. If you suspect that you may be in possession of counterfeit PROCRTIT, you should immediately contact your wholesaler/supplier regarding refund for the product.

If you have medical questions regarding suspected counterfeit PROCRTIT, please contact Ortho Biotech Medical Information at 1 (800) 325-7504, prompt #2.

OBPLP is cooperating fully with the FDA to investigate this matter and prevent the further distribution of counterfeit product. As of June 6, 2002, OBPLP is aware of the distribution of counterfeit product in the U.S. only.

**Full product information and updates on this situation will be available at [www.procrit.com](http://www.procrit.com) or [www.orthobiotech.com](http://www.orthobiotech.com). For those who do not have Internet access, please contact Ortho Biotech Medical Information at 1 800 325-7504, prompt #2**

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Other Contact Information: U.S. Food and Drug Administration (for press inquiries): (301) 827-6242

\*PROCRTIT is the brand name of epoetin alfa manufactured by Amgen Inc., and marketed by Ortho Biotech Products, L.P.