

May 17, 2001

Serono, Inc.  
100 Longwater Circle  
Norwell, MA 02061  
Tel. 781 982 9000  
Fax 781 871 6754  
[www.seronousa.com](http://www.seronousa.com)

### **INFORMATION ON NEW COUNTERFEIT SEROSTIM® LOT**

Dear Doctor:

Serono, Inc. and the U.S. Food and Drug Administration (FDA) are informing distributors, pharmacies, physicians and patients of the existence of a new counterfeit lot of Serono's Serostim® 6 mg [somatropin (rDNA origin) for injection]. The counterfeit material, which is made to resemble Serostim®, bears lot number MNH605A. Any product labeled as Serostim® and carrying this lot number should be considered to be counterfeit.

Patients in possession of the counterfeit lot should return it immediately to their pharmacy for a replacement. Patients seeking additional information may also call Serono's product information line at 1-888-275-7376.

Serono is sending a "Notification of Counterfeit Product" letter to wholesale distributors, pharmacies, physicians and AIDS service organizations to alert them. The counterfeit material was neither manufactured nor distributed by Serono and is definitely not Serostim®. Therefore, it cannot be assumed that the counterfeit product is either safe or effective.

Serono is cooperating fully with the FDA in its effort to stop the distribution of the counterfeit product and to prosecute those responsible for it.

If you are concerned that one of your patients may have received the counterfeit lot, please call Serono at 1-888-275-7376.

Sincerely,

**(ELECTRONIC COPY)**

Pamela Williamson Joyce  
Vice President, Regulatory Affairs  
Serono, Inc.