



NDA 20-604/S-044

EMD Serono, Inc.
Attention: Lisa Mills
Director, Regulatory Affairs
One Technology Place
Rockland, MA 02370

Dear Ms. Mills:

Please refer to your supplemental new drug application dated June 7, 2007 received June 7, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serostim (somatropin [rDNA origin] for injection).

We acknowledge receipt of your submission dated July 20, 2007, containing revised labeling (carton and package insert).

This "Changes Being Effected" supplemental new drug application provides for a 4-vial package of the 8.8 mg strength vial and accompanying diluent and revisions to the HOW SUPPLIED section of the package insert to reflect this addition.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved supplemental NDA 19-764/S-044."

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your June 7, 2007 submission containing final printed container (vial) labels, and your July 20, 2007, submission containing final printed carton labels.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Container (Vial) Label, 8.8 mg, submitted June 7, 2007
Carton Label, 8.8 mg, 4 vials/package, submitted July 20, 2007
Package Insert, submitted July 20, 2007

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Mary Parks
8/30/2007 06:49:32 AM