



NDA 20-604/S-035

Serono, Inc.
Attention: Pamela Williamson Joyce
VP, Regulatory Affairs & QA-US
One Technology Place
Rockland, MA 02370

Dear Ms. Joyce:

Please refer to your supplemental new drug application dated April 25, 2005, received April 26, 2005, 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 submissions dated November 10, 2005, October 20 and November 14, 2006.

Your submission of November 10, 2005 constituted a complete response to our August 26, 2005 action letter.

This supplemental new drug application provides for a 4 mg multidose vial packaged in 1- and 7-vial kits containing equal numbers of vials of Bacteriostatic Water for Injection, USP as the diluent.

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 attached agreed-upon labeling text. Submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert (submitted October 20, 2006, immediate container (vial) and carton labels submitted November 14, 2006, and diluent label submitted October 20, 2006).

Please submit an electronic version or 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-604/S-035.**" Approval of this submission by FDA is not required before the labeling is used.

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, Chief, Project Management Staff 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: Package Insert (October 2006)
 4 mg vial label (L64201XX)
 1-vial kit carton (somatropin & diluent) (E64201XXX)
 7-vial kit carton (somatropin & diluent) (E6420102)
 Diluent (Bacteriostatic Water for Injection, USP) Label (401755B)

**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

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