



NDA 20-604/S-031

Serono, Inc.
Attention: Pamela Williamson Joyce
One Technology Place
Rockland, MA 02370

Dear Ms. Williamson Joyce:

Please refer to your supplemental new drug application dated December 23, 2003, received January 14, 2004, 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 February 24 and August 1, 2005.

Your submission of February 24, 2005 constituted a complete response to our July 14, 2004 action letter.

This supplemental new drug application provides for a patient package insert (PPI) for Zorbtive (somatropin [rDNA origin] for injection), approved under NDA 21-597 as a type 6 NDA on December 1, 2003, which was simultaneously incorporated into NDA 20-604 with the approval of supplement -026.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the patient package insert) revised as follows:

- Under **What are the possible side effects of Zorbtive™**, under "Pancreatitis", correct "sever" to read "severe"
- Under **How Do I Store Zorbtive™**, add the trademark symbol and a question mark.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 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-031.**" 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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) 827-6380.

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD
Director
Division of Metabolic & Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Patient Package Insert

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

/s/

David Orloff

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