



NDA 19-764/S-025
NDA 20-604/S-030

Serono, Inc.
Attention: Pamela Williamson-Joyce
Vice President, Regulatory Affairs & Quality Assurance
One Technology Place
Rockland, MA 02370

Dear Ms. Joyce:

Please refer to your supplemental new drug applications dated August 29, 2003, and received September 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Saizen (somatropin [rDNA origin] for injection), and Serostim (somatropin [rDNA origin] for injection) respectively.

We acknowledge receipt of your submissions dated September 23, and 24, November 17, and 25, December 1, and 23, 2003, and March 10, June 15 and 25, 2004.

Your submission of March 10, 2004, constituted a complete response to our January 2, 2004 action letter.

These supplemental new drug applications provide for (1) an additional drug product manufacturing facility in Farmaceutica Serono S.p.A. in Bari, Italy (IFS- Bari); (2) a new drug delivery system consisting of a pre-assembled reconstitution device called the 'Click.easy' which contains a vial of Saizen or Serostim and a cartridge of 0.3% (w/ v) metacresol in Water for Injection; and (3) an auto-injector pen called the 'One.click' to be used exclusively with the Click.easy.

We completed our review of these applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon draft labeling text and with the minor editorial revisions listed below.

1. Please revise all the labeling to accurately reflect the total drug content as 8.8 mg. A statement can be added that indicates "approximately 8 mg of the drug is delivered."
2. Please revise all the labeling with the following: "Once reconstituted, store the cartridge in the refrigerator (2-8°/36-46°F) and use within 21 days after reconstitution. Do not freeze."

The final printed labeling (FPL) must be identical to the enclosed labeling, and include the minor editorial revisions indicated, to the text for the package insert, submitted on June 25, 2004, the instruction for use for both the One.click auto-injector and the Click.easy reconstitution device, the cartridge labels, carton labels and vial labels submitted on March 10, 2004.

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Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-764/S-025 and NDA 20-604/S-030." Approval of these submissions 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 Monika Johnson, Regulatory Project Manager, at (301) 827-9087.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug
Products (HFD-510)
Office of New Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

- A. Package Insert
- B. Click.easy Reconstitution Device Instructions for Use
- C. One.click Auto-injector Instructions for Use
- D. Carton label
- E. Cartridge label
- F. Vial Label

**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
7/9/04 03:44:13 PM
for Dr. Orloff