



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-604/S-029

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 application dated March 28, 2003, received, March 31, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serostim LQ (somatropin [rDNA origin] injection), 6 mg/0.5 mL cartridge.

Your submission of October 13, 2004, constituted a complete response to our August 20, 2004, action letter.

This supplemental new drug application provides for the addition of a liquid injectable formulation.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the directions for use of Serostim LQ for patients, immediate container and carton labels) which were submitted October 12, 2004.

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, this submission should be designated "FPL for approved supplement NDA 20-604/S-029." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated October 12, 2004. These commitments are listed below.

1. Conduct an immunogenicity study in patients with HIV-associated wasting.

Protocol Submission:	Final proposed protocol within 60 days after approval of S-029
Study Start:	initiate and complete study within two year after approval of S-029
Final Report Submission:	6 months after study completion

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **“Postmarketing Study Protocol”**, **“Postmarketing Study Final Report”**, or **“Postmarketing Study Correspondence.”**

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 Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

David Orloff
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