



NDA 20-604/S-034

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

Dear Ms. Joyce:

Please refer to your supplemental new drug application dated April 15, 2005, received April 18, 2005, 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.

We acknowledge receipt of your submissions dated August 17 and 26, 2005, and April 13 and August 21, 2006.

Your submission of August 21, 2006 constituted a complete response to our August 14, 2006 action letter.

This supplemental new drug application provides alternate room temperature storage (up to 7 days) for the cartridge after it is dispensed to the patient.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the attached final printed labeling (FPL) submitted on April 13, 2006.

We remind you that you must comply with the requirements for an approved NDA set forth under 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, M.D.  
Director  
Division of Metabolism & Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Attachment: Package Insert  
1-cartridge carton label  
7-cartridge carton label

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

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Mary Parks  
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