



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 19-764/S-020

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

Dear Ms. Joyce:

Please refer to your supplemental new drug application dated June 28, 2002, received July 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Saizen (somatropin [rDNA origin] for injection).

We acknowledge receipt of your submission dated October 26, 2004, which constituted a complete response to our August 26, 2004, tentative approval letter.

This supplemental new drug application provides for the use of Saizen for the replacement of endogenous growth hormone in adults with growth hormone deficiency.

We completed our review of this application, as amended 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 (package insert submitted October 26, 2004).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs*. 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 19-764/S-020." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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 Enid Galliers, Chief, Project Management Staff, at 301-827-6429.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure: Package Insert

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

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David Orloff

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