DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-764/S-030

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 July 28, 2005 received July 29, 2005, 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 submissions dated March 3, May 26, November 16, and December 14, 2006

Your submission of May 26, 2006 constituted a complete response to our November 22, 2005 action letter.

This supplemental new drug application provides for the addition of two new presentation (4 mg and 8 mg) of Saizen cartridges contained in the click.easy reconstitution device.

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 enclosed agreed-upon labeling text. Submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text which you submitted by email on November 16, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

The final printed labeling (FPL) must be identical to the enclosed draft labeling.

Please submit either an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If paper copies are submitted, individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission **"FPL for approved NDA 19-764/S-030"** Approval of this submission by FDA is not required before the labeling is used.

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:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary Parks, MD
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation
Center for Drug Evaluation and Research

Enclosure: Package Insert
Container (vial) label- 4 mg (1.5 mg/ml)
Container (vial) label- 8.8 mg (8 mg/ml)
Diluent label-2.66 ml, for use with 4 mg vial
Diluent label-1.10 ml, for use with 8 mg vial
click.easy reconstitution device carton-4 mg, 1 vial somatropin + 1 vial diluent
click.easy reconstitution device carton-4 mg, 5 vials somatropin + 5 vials diluent
click.easy reconstitution device carton-8 mg, 1 vial somatropin + 1 vial diluent
click.easy reconstitution device carton-8 mg, 5 vials somatropin + 5 vials diluent
Instructions for Use-click.easy Reconstitution Device

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

1/16/2007 10:19:28 AM