DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-764/S-037

EMD Serono, Inc.
Attention: Paul Lammers, MD
Acting Head, Regulatory Affairs and Quality Assurance
One Technology Place
Rockland, MA 02370

Dear Dr. Lammers:

Please refer to your supplemental new drug application dated March 2, 2007, received March 5, 2007, 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 July 13, 2007, containing a revised package insert which includes the revisions approved in Supplement -034 on March 5, 2007.

This supplemental new drug application provides for revision to the DOSAGE AND ADMINISTRATION section, Pediatric Growth Hormone Deficiency (GHD) subsection, to state the total weekly dose with options to administer the drug 3 times per week, 6 times per week, or daily.

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 agreed-upon labeling text.

CONTENT OF LABELING
As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the submitted, enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved supplemental NDA 19-764/S-037."

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

Enclosure: Package insert, submitted July 13, 2007

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

/s/

Hylton Joffe
8/22/2007 01:23:34 PM
Hylton Joffe for Mary Parks