DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-764/S-039

EMD Serono, Inc.
Attention: Lisa Mills
Director, Regulatory Affairs
One Technology Place
Rockland, MA 02370

Dear Ms. Mills:

Please refer to your supplemental new drug application dated April 30, 2007, received May 1, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Saizen (somatropin [rDNA origin] for injection).

This "Changes Being Effected" supplemental new drug application provides for revised container (vial) and carton labeling to add the concentration (5.83 mg/ml) to the click.easy® reconstitution device approved in supplement -025 on July 9, 2004.

We completed our review of this supplemental new drug application. It is are approved, effective on the date of this letter, for use as recommended in the attached final printed labeling (FPL) submitted on April 30, 2007.

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 the requirements for an approved NDA set forth under 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: Vial Label (L1280101C, 03/07)
Carton (E1280101C, 03/2007)

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

8/27/2007 10:09:31 AM