DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-764/S-034

EMDSerono, Inc.
Attention: Paul Lammers, MD
Acting Head, Regulatory Affairs and QA, US
One Technology Place
Rockland, MA 02370

Dear Dr. Lammers:

Please refer to your supplemental new drug application dated June 30, 2006, received July 3, 2006, 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 February 6, 2007, containing the labeling revisions approved in Supplement-030 on January 16, 2007.

This "Changes Being Effected" supplemental new drug application provides for harmonized growth hormone labeling, particularly involving the CONTRAINDICATION, WARNINGS, and PRECAUTIONS sections of the package insert.

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 final printed labeling (FPL) submitted on February 6, 2007.

In addition, at the next printing:

1. Delete reference to "long term" with respect to treatment for any indication, since this terminology is not used with other products given for chronic use.
2. In the following sentence in the CONTRAINDICATIONS section, delete the hyphen in "pre-existing": "Any pre-existing malignancy should be inactive and its treatment complete prior to instituting therapy with somatropin."
3. In the DOSAGE AND ADMINISTRATION section, Adult Patient subsection, delete "more" from the following sentence: "Alternatively, taking into account more recent literature, a starting dose of approximately 0.2 mg/day…"
4. Revise the Stability and Storage section so that it mentions the shelflife of the 4 mg click.easy cartridge, approved in Supplement -030, following reconstitution.

Within 21 days of the date of this letter, 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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 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 (February 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

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