



NDA 19-764/S-035

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

Dear Mr. Kirsch:

Please refer to your supplemental new drug application dated August 2, 2006, received August 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 submissions dated March 30 and October 3, 2007.

Your submission of March 30, 2007 constituted a complete response to our January 25, 2007 action letter.

This supplemental new drug application provides for easypod, an auto-injection pen device which administers a preset dose of Saizen using the currently approved click.easy cartridges.

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(1)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert, patient package insert [click.easy Instructions for Use], and device labeling [Easypod Instructions for Use]). 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-035".

Submit final easypod carton labeling that is identical to the enclosed labeling as soon as it is available, but no more than 30 days after it is printed. Please submit this labeling electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling-easypod carton for approved NDA supplement 19-764/S-035.**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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

Enclosures: Package Insert/Patient Package Insert (click.easy Instructions for Use)
Easypod Instructions for Use
Easypod carton

**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
10/31/2007 08:51:56 AM