



NDA 19-774/S-014

Ferring Pharmaceuticals, Inc.
Attention: James H. Conover, PhD
Executive Director, Regulatory Affairs
400 Rella Boulevard, Suite 300
Suffern, NY 10901

Dear Dr. Conover:

Please refer to your supplemental new drug application dated October 27, 2006, received October 31, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tev-Tropin (somatropin [rDNA origin] for injection).

We acknowledge receipt of your submission dated January 30, 2007.

This supplemental new drug application provides for harmonization of somatropin labeling, particularly involving the CONTRAINDICATIONS and WARNINGS 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 attached final printed labeling (FPL) submitted on January 30, 2007.

At the next printing, please make the following changes:

1. Delete all reference to "long term" with respect to treatment, 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 PRECAUTIONS section, Geriatric Use subsection, delete (see DOSAGE AND ADMINISTRATION), currently located at the end of the paragraph.

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 and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert, Rev. H 6/2006

**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
2/15/2007 07:10:31 AM