



NDA 21-426/S-006

Sandoz Inc.  
Attention: Jean Domenico  
Senior Associate, Regulatory Affairs  
2555 W. Midway Blvd., P.O. Box 446  
Broomfield, CO 80038-0446

**SUPPLEMENT APPROVAL**

Dear Ms. Domenico:

Please refer to your supplemental new drug application dated November 24, 2008, received November 25, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omnitrope (somatropin [rDNA origin] for injection and cartridges).

We acknowledge receipt of your submission dated January 6, 2009, containing a revised package insert.

This supplemental new drug application provides for extending the in-use expiration dating period for the 5 mg/1.5 ml cartridge, for administration with Omnitrope Pen 5 Delivery system, from 21 to 28 days.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed 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 enclosed labeling (text for the package insert, 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 NDA 21-426/S-006.**"

**CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed container labels that are identical to the enclosed immediate container and carton labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 Carton and Container Labels for approved NDA 21-426/S-006.**” Approval of this submission by FDA is not required before the labeling is used.

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

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
5600 Fishers Lane; Room 12B05  
Rockville, MD 20857

**REPORTING REQUIREMENTS**

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, M.D.  
Director  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure: Package Insert  
Omnitrope Pen 5-Instructions for Use  
Cartridge Label, 5 mg/1.5 mL  
Carton Label, 5 mg/1.5 mL (1 cartridge)  
Carton Label, 5 mg/1.5 mL (5 cartridges)  
Carton Label, 5 mg/1.5 mL (10 cartridges)

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this page is the manifestation of the electronic signature.**  
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/s/

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Mary Parks  
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