



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-426/S-004

Sandoz, Inc  
Attention: Beth Brannan  
Director, Regulatory Affairs  
2555 W. Midway Blvd., P.O. Box 446  
Broomfield, CO 80038

Dear Ms. Brannan:

Please refer to your supplemental new drug application dated March 28, 2008, received March 31, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Omnitrope (somatropin [rDNA origin] for injection) and Omnitrope (somatropin [rDNA origin] injection).

We acknowledge receipt of your submissions dated April 22, and July 30, 2008.

This supplemental new drug application provides for a new strength cartridge (10 mg/1.5 mL) of the liquid formulation for use in a new reusable injector pen, Omnitrope Pen 10.

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.

The final printed labeling (FPL) for the package insert and Instructions for Use must be identical to the enclosed labeling. The FPL for the cartridge label, cartridge cartons, and pen device carton is acceptable.

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  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

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  
                  Instructions for Use-Omnitrope Pen 10  
                  Omnitrope Pen 10 Carton  
                  Omnitrope Cartridge (10 mg/1.5 mL) Label  
                  Omnitrope Cartridge (10 mg/1.5 mL) Carton (1-count)  
                  Omnitrope Cartridge (10 mg/1.5 mL) Carton (5-count)  
                  Omnitrope Cartridge (10 mg/1.5 mL) Carton (10-count)

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Mary Parks

8/25/2008 11:56:29 AM