CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-426

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-426

Sandoz Inc.
Attention: Beth Brannan
Sandoz Inc.
2555 W. Midway Blvd.
Broomfield, CO 80038

Dear Ms. Brannan:

Please refer to your new drug application (NDA) dated December 27, 2001, resubmitted July 30, 2003, received July 31, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Omnitrope (somatropin [rDNA origin]) for injection, 1.5 mg/vial and 5.8 mg/vial.

We acknowledge receipt of your submissions dated November 29 and December 1, 2004; February 9 and 10 and March 17 and 22, 2005; and April 27 and May 1, 4, 12, 16, and 17, 2006.

Your application proposes Omnitrope (somatropin [rDNA origin]) for injection, 1.5 mg/vial and 5.8 mg/vial, for (1) long-term treatment of pediatric patients who have growth failure due to inadequate secretion of endogenous growth hormone and (2) long-term replacement in adults with growth hormone deficiency of either childhood or adult onset etiology.

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 agreed-upon labeling text and with the minor editorial revisions listed below.

1. Carton Label, **1.5 mg/vial**: replace the phrase "1 vial Water for Injection" with "1 vial Sterile Water for Injection" on both major panels and replace the phrase "1.13 mL water for injection" with "1.13 mL Sterile Water for Injection" on the side panel.

The final printed labeling (FPL) must be identical to, except for the revisions listed above, the enclosed labeling (text for the package insert and patient instructions for use) and the enclosed submitted labeling (immediate container [1.5 mg/vial and 5.8 mg/vial] labels submitted May 12, 2006, both diluent labels submitted May 12, 2006, the 1.5 mg/vial and 5.8 mg/vial carton labels submitted May 12, 2006). These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as stated, in the product's labeling may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-426**." Approval of this submission by FDA is not required before the labeling is used.

We request that you submit the content of labeling as structured product labeling (SPL). Among the guidances for industry available at the FDA/CDER website, you may find the following two documents useful: *Providing Regulatory Submissions in Electronic Format – Content of Labeling* and *SPL Standard for Content of Labeling: Technical Q's & A's.*

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for children less than three years of age and greater than 13 years of age. We note that you have fulfilled the pediatric study requirement for this application.

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 (**DMEP**) 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

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 Enid Galliers, Chief, Project Management Staff, DMEP, at (301) 796-1211.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Prescribing Information
Instructions for Use (1.5 mg/vial), (5.8 mg/vial)
Vial Labels (1.5 mg/vial), (5.8 mg/vial)
Diluent Labels (Sterile Water for Injection), (Bacteriostatic Water for Injection)
Carton Labels (1 x 1.5 mg/vial and diluent); (8 x [5.8 mg/vial and diluent])

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Meyer
5/30/2006 05:53:01 PM