



NDA 021426/S-007 & S-008

**SUPPLEMENT APPROVAL**

Sandoz Inc.  
Attention: John Pakulski, R.Ph.  
Director - Specialty Biologics, Regulatory Affairs  
506 Carnegie Center, Suite 400  
Princeton, NJ 08540

Dear Mr. Pakulski:

Please refer to your supplemental new drug applications dated November 24, 2008, received June 23, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Omnitrope (somatropin [rDNA origin] injection), 1.5 mg/vial and 5.8 mg/vial; and 5 mg/1.5 mL and 10 mg/1.5 mL Cartridges.

We acknowledge receipt of your submissions dated June 26 and October 13, 2009, and March 17, and April 23(email), 2010.

These "Prior Approval" supplemental new drug applications provide for addition of the following new indications:

Supplement-007 to treat children with short stature who have Prader-Willi syndrome (PWS)

Supplement-008 to treat children with short stature who were born small for their gestational age (SGA).

We have completed our review of these supplemental applications, as amended. They are 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, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert and text for the patient instructions for use) and include any labeling changes proposed in pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at

<http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA that include labeling, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(1)(1)(i)] in *MS Word* format that includes the changes approved in these supplemental applications.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indications in pediatric patients unless this requirement is waived, deferred, or inapplicable.

This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instructions on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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

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:

Content of Labeling:  
Package Insert  
Instructions for Use

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- NDA-21426	----- SUPPL-8	----- SANDOZ INC	----- OMNITROPE(SOMATROPIN[RD NA ORIGIN] FORINJ
NDA-21426	SUPPL-7	SANDOZ INC	OMNITROPE(SOMATROPIN[RD NA ORIGIN] FORINJ

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

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/s/  
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MARY H PARKS  
04/23/2010