

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-028

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-028

NDA APPROVAL

Sandoz Inc.
Attention: Beth Brannan
Director, Regulatory Affairs
2555 W. Midway Blvd; P.O. Box 446
Broomfield, CO 80038-0446

Dear Ms. Brannan:

Please refer to your new drug application (NDA) dated February 3, 2006, received February 6, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Cosyntropin (α 1-24 corticotropin) Injection, 0.25 mg/mL.

We acknowledge receipt of your submissions dated December 4, 2006, August 20, September 17, October 15, December 6, (2) and December 21, 2007, and February 12, and 15, 2008.

The August 20, 2007, submission constituted a complete response to our December 6, 2006, action letter.

This new drug application provides for the use of Cosyntropin Injection as a diagnostic agent in the screening of patients presumed to have adrenocortical insufficiency.

We acknowledge your December 4, 2006, submission containing final printed carton and container labels.

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.

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 dated February 12, 2008.) 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 22-028."**

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 indication in pediatric patients unless this requirement is waived, deferred, or inapplicable. This drug is fully labeled for use in all appropriate pediatric populations. Therefore, no additional pediatric studies are needed at this time.

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 instruction 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 www.fda.gov/cder/ddmac.

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
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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, please call Ms. Jena Weber, Regulatory Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

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

Enclosure

**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

2/21/2008 09:56:14 AM