DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-466/S-036

Sandoz Canada, Inc.
2555 W. Midway Blvd.
P.O. Box 446
Broomfield, CO 80038-0446

Attention: Beth Brannan
Director, Regulatory Affairs
US Authorized Agent

Dear Ms. Brannan:

Please refer to your supplemental new drug application dated August 31, 2006, received September 1, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ARISTOSPAN® (triamcinolone hexacetonide injectable suspension USP), 5 and 20 mg/mL.

This "Changes Being Effected" supplemental new drug application provides for inclusion of benzyl alcohol paragraphs in the WARNINGS and PRECAUTIONS sections of the label and revisions to HOW SUPPLIED sections, and manufacturer's statement.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text for the package insert. For administrative purposes, designate this submission **"Content of Labeling for approved NDA 16-466/S-036."** Upon receipt and verification that the content of labeling in SPL format is identical to the approved labeling text, we will transmit that version to the National Library of Medicine for public dissemination.

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
5515 Security Lane
HFD-001, Suite 5100
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, call Paul Z. Balcer, Regulatory Project Manager, at (301) 796 1173.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures

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

/s/

Bob Rappaport

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