DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
SIlver Spring, MD 20993

SUPPLEMENTAL **NDA APPROVAL**

NDA 16-466/S-040
NDA 16-466/S-041

Sandoz, Inc
2555 W. Midway Blvd.
Broomfield, CO 80038

Attention: Beth Brannon
Director, Drug Regulatory Affairs

Dear Ms. Brennon:

Please refer to your supplemental new drug applications dated August 22 and 27, 2008, received August 25 and 28, 2008, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aristospan (triamcinolone hexacetanide Injectable Suspension, USP) 5 mg/mL and 20 mg/mL.

We acknowledge receipt of your submissions dated August 22 and 27, 2008.

These "Changes Being Effected" supplemental new drug applications provide for the revisions to the **WARNINGS** section of the Package Insert.

We have completed our review of these applications, as amended, and 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, 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. 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 NDA 16-466/S-040"** and **"SPL for approved NDA 16-466/S-041**."

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
Suite 12B05
5600 Fishers Lane
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 Christopher Hilfiger, Regulatory Project Manager, at (301) 796-4131.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, MD
Director
Division of Anesthesia, Analgesia and
Rheumatology 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/

Rigoberto Roca
6/3/2009 11:25:56 AM
for Bob Rappaport, M.D.