DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-466/S-027

Sabex Pharmaceutical Products
C/O Sandoz Pharmaceuticals, Inc.
2555, W. Midway Blvd
Broomfield, CO 80038

Attention: Beth Brannan
Director, Regulatory Affairs
U.S. Agent

Dear Ms. Brannan:

Please refer to your supplemental new drug applications dated November 30, 1992, received December 3, 1992, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aristopan (triamcinolone hexacetonide injectabale suspension) 5 mg/mL and 20 mg/mL.

We acknowledge receipt of your submissions dated January 20, 1993, and October 9, 2002.

Your submission of October 9, 2002, constituted a complete response to our July 3, 2001, action letter.

This "Changes Being Effected" supplemental new drug application provides for a revised **ADVERSE REACTIONS** section of the package insert.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul Balcer, Regulatory Project Manager, at (301) 796-1173.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
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/

Bob Rappaport

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