DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-148/S-030 and S-035
NDA 20-409/S-005 and S-011

Ivax Research, Inc.
4400 Biscayne Blvd.
Miami, Florida 33137

Attention: Steve Viti, Ph.D.
Director Regulatory Affairs

Dear Dr. Viti:

Please refer to your supplemental new drug applications dated January 13, 1999 and September 27, 2000, received January 14, 1999, and September 27, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasalide (flunisolide) Nasal Spray, and Nasarel (flunisolide) Nasal Spray.

We acknowledge receipt of your submissions dated September 21, 2000. Your submission of September 21, 2000, constituted a complete response to our August 25, 2000, action letter for NDA 18-148/S-030 and NDA 20-409/S-005.

These supplemental new drug applications provide for:

NDA 18-148/S-030 and NDA 20-409/S-005: Revisions to the PRECAUTIONS and ADVERSE REACTIONS sections of the package inserts to include information on the growth suppressive effects of inhaled corticosteroids, as requested in our letter dated November 6, 1998.

NDA 18-148/S-035 and NDA 20-409/S-011: Revised labeling in response to the August 27, 1997, Federal Register, requesting the addition of a Geriatric Use subsection to the package insert.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must combine the revisions contained in the submitted draft labeling (package inserts submitted September 21 and 27, 2000).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 18-148/S-030 and S-035, 20-409/S-005 and S-011." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Mrs. Sandy Barnes, Chief, Project Management Staff, at (301) 827-1055.

Sincerely,

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Office of New Drugs

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

/s/

Robert Meyer

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