DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-457/S-002 & S-004

IVAX Research, Inc.
4400 Biscayne Boulevard
Miami, Florida 33137

Attention: Steven M. Viti, Ph.D.
Director, Regulatory Affairs

Dear Dr. Viti:

Please refer to your supplemental new drug applications dated March 18 (S-002), and May 5, 2005 (S-004), received March 21 (S-002), and May 6, 2005 (S-004), submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act for ProAir™ HFA (albuterol sulfate) Inhalation Aerosol.

We acknowledge receipt of your submissions dated October 6, 2005, to Supplement 002, and May 21, July 26, and October 6, 2005, to Supplement 004.

These supplemental new drug applications provide for the addition of the trade name ProAir HFA to the package insert, patient instructions for use, and carton and container labeling, and changes to the onset of action in the package insert.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below and agreed to in a telephone conversation on November 7, and November 21, 2005.

1. Revise the fourth sentence of second paragraph of the DESCRIPTION section to "……salbutamol sulfate is the World Health Organization recommended generic name."

2. Revise the second sentence of the Special Populations: Renal Impairment subsection of the CLINICAL PHARMACOLOGY section to "Renal disease had no effect……"

3. Revise the heading of column two of the Adverse Reaction table in the ADVERSE REACTONS section to include HFA in the tradename.

The final printed labeling (FPL) must be identical, except to include the minor editorial revisions indicated above, to the submitted labeling (package insert, patient instructions for use, and immediate container and carton labels submitted October 6, 2005). These revisions are terms of the approval of these applications.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 21-457/S-002, S-004**." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Pulmonary and Allergy Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Ms. Akilah Green, Regulatory Management Officer, at (301) 796-1219.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy 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/

Eugene Sullivan
11/21/2005 05:06:21 PM
For Badrul Chowdhury