DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-409/S-022

IVAX Research, Inc.
Attention: Steven M. Viti, PhD, MBA
Senior Director, Global Respiratory Regulatory Affairs
4400 Biscayne Boulevard
Miami, FL 33137-3212

Dear Dr. Viti:

Please refer to your supplemental new drug application dated September 14, 2007, received September 17, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NASAREL® (flunisolide) Spray Metered, 29mcg/actuation.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for using new flunisolide hemihydrate USP manufactured by [redacted]

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Robert Hummel, Regulatory Health Project Manager for Quality, at (301) 796-1981.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

Jim Vidra

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