DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-519

IVAX Pharmaceuticals, Inc.
An indirect, wholly owned subsidiary of TEVA Pharmaceuticals USA
Attention: Patricia Jaworski
Senior Director, Regulatory Affairs
U.S. Agent for IVAX Pharmaceuticals, UK
Two University Plaza, Suite 220
Hackensack, NJ 07601

Dear Madam:

This letter corrects our approval letter of November 18, 2008, in which we incorrectly requested dissolution testing for your drug product. This letter replaces the previous letter and is backdated to the date of the original approval letter, November 18, 2008.

This is in reference to your abbreviated new drug application (ANDA) dated December 30, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Budesonide Inhalation Suspension, 0.25 mg/2 mL and 0.5 mg/2 mL Unit-dose Vials.

Reference is also made to your amendments dated February 9 and 21, March 19 and 21, April 23, September 6, 21 (two submissions), and 27, 2007; and February 4, March 4, July 2 and 24, August 5, September 22, and November 7, 2008. We also acknowledge receipt of your correspondences dated September 14, 2005; July 5, 2006; March 7, and November 18, 2008 addressing the patent issues associated with this ANDA.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Budesonide Inhalation Suspension, 0.25 mg/2 mL and 0.5 mg/2 mL Unit-dose Vials to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Pulmicort Respules Inhalation Suspension, of AstraZeneca.

The RLD upon which you have based your ANDA, AstraZeneca's Pulmicort Respules Inhalation Suspension, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations

(the "Orange Book"), U.S. Patent Nos. 6,598,603 (the '603 patent) and 6,899,099 (the '099 patent) are both scheduled to expire (with pediatric exclusivity added) on June 23, 2019. Your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act that the '603 and '099 patents are method of use patents that do not claim any method of use for which you are seeking approval.[1]

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 2070

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] The agency is aware that, as a result of an earlier paragraph IV certification, litigation was initiated against IVAX Pharmaceuticals, Inc. for infringement of the '099 patent in the United States District Court for the District of New Jersey [Civil Action No. 05-CV-05142-JBS-AMD], and that this litigation is ongoing.

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

/s/

Gary Buehler

11/18/2008 03:22:28 AM