DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 65-110

MAR 29 2005

IVAX Pharmaceuticals Inc.
Attention: Patricia Jaworski
U.S. Agent for: IVAX Pharmaceuticals s.r.o.
125 Wells Avenue
Congers, NY 10920

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 31, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Cyclosporine Capsules USP (Modified), 25 mg, 50 mg, and 100 mg. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated July 15, August 2, December 4, and December 12, 2002; January 15, February 11, February 26, and June 6, 2003; March 23, June 24, June 29, June 30, and August 24, 2004; and March 17, 2005.

Reference is also made to the ANDA suitability petition submitted under Section 505(j)(2)(c) of the Act requesting the agency to determine whether Novartis Pharmaceuticals Corporation's Neoral Soft Gelatin Capsules, 50 mg, were withdrawn from sale for reasons of safety or effectiveness. This drug product currently appears in the "Discontinued" section of the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book". The agency determined that they were not withdrawn from sale for reasons of safety or effectiveness. This determination permitted you to file this ANDA, and allows the agency to approve ANDAs for Cyclosporine Capsules USP (Modified), 50 mg.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Cyclosporine Capsules USP (Modified), 25 mg,

and 100 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Neoral® Soft Gelatin Capsules, 25 mg, and 100 mg, respectively, of Novartis Pharmaceuticals, Corp.). The Division of Bioequivalence has also determined that your Cyclosporine Capsules USP (Modified), 50 mg, can be expected to have the same therapeutic effect as that of an equivalent dose of the reference listed drug product upon which the agency relied as the basis of safety and effectiveness. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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

Post-marketing reporting requirements for this abbreviated application 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
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

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