DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-468

APR 18 2005

IVAX Pharmaceuticals, Inc.
Attention: Patricia Jaworski
Director, Regulatory Affairs
125 Wells Avenue
Congers, NY 10920

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated July 30, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Anagrelide Hydrochloride Capsules, 0.5 mg (base) and 1 mg (base).

Reference is also made to your amendments dated January 6, 2003; June 17, November 18, and December 3, 2004; and January 10, February 18, and March 11, 2005.

The listed drug (RLD) referenced in your application, Agrylin Capsules of Shire Laboratories, Inc., is subject to a period of exclusivity. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", Shire's three-year exclusivity with respect to labeling providing for the use of Agrylin Capsules in the pediatric patient population, (M-39), will expire on June 10, 2008. Section 11 of the Best Pharmaceuticals for Children Act (BPCA), signed into law in January 2002, allows certain portions of Shire's labeling which is the subject of pediatric exclusivity protection to be omitted from the labeling of products approved under section 505(j). The BPCA also permits the addition of language to the labeling of products approved under section 505(j) that informs health care practitioners that Shire's product has been approved for pediatric use. The agency has determined that the final printed labeling you have submitted is in compliance with the BPCA with respect to pediatric use protected by exclusivity.

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 Anagrelide Hydrochloride Capsules, 0.5 mg (base) and 1 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Agrylin® Capsules 0.5 mg (base) and 1 mg (base), respectively, of Shire Laboratories, Inc.). 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.

Postmarketing 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