DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-333/S-016

SUPPLEMENT APPROVAL

Shire Development, Inc.
Attention: Linda Moto
Manager, Global Regulatory Affairs
725 Chesterbrook Blvd.
Wayne, PA 19087

Dear Ms. Moto:

Please refer to your Supplemental New Drug Application (sNDA) dated February 5, 2010, received February 5, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Agrylin® (anagrelide hydrochloride) Capsules.

We acknowledge receipt of your amendments dated February 17, April 7 and June 22, 2010.

This "Prior Approval" supplemental new drug application provides for addition of hepatotoxicity in the Laboratory Tests subsection of the Precautions section and Postmarketing Reports subsection of the Adverse Reactions section.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below and indicated in the enclosed labeling.

In the Precautions section, Laboratory Tests subsection, in the last sentence of the first paragraph that begins with "Measure liver functions tests (ALT, AST) before initiating anagrelide treatment and …" the "liver functions tests" should read "liver function tests".

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Hyon-Zu Lee, Pharm.D., Regulatory Project Manager, at 301-796-2192.

Sincerely,

{See appended electronic signature page}

Ann Farrell, M.D.
Acting Director
Division of Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure:

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20333	SUPPL-16	SHIRE DEVELOPMENT INC	AGRYLIN

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

/s/

ANN T FARRELL
06/30/2010