



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

September 3, 2004

Alan Minsk
Arnall Golden Gregory LLP
2800 One Atlantic Center
1201 West Peachtree Street
Atlanta, GA 30309-3450

FILE COPY

Dear Mr. Minsk:

Your petition submitted on behalf of Shire US, Inc., requesting the Food and Drug Administration to stay the approval of any abbreviated new drug application (ANDA) for Agrylin (anagrelide hydrochloride) capsules until it has reviewed and responded to the citizen petition dated August 13, 2004, was received by this office on 09/03/2004. It was assigned docket number 2004P-0365/PSA1 and it was filed on 09/03/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2004P-0365

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