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Food and Drug Administration  
Rockville, MD 20857

August 16, 2004

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

Dear Mr. Minsk:

Your petition submitted on behalf of Shire US, Inc., requesting the Food and Drug Administration to refrain from approving any abbreviated new drug application (ANDA) for Agrylin (anagrelide hydrochloride) capsules that fail to include active metabolite monitoring in bioequivalency testing, was received by this office on 08/16/2004. It was assigned docket number 2004P-0365/CP1 and it was filed on 08/16/2004. 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,

Gloria Ortega  
Division of Dockets Management  
Office of Management Programs  
Office of Management