

ANDA 75-936

October 17, 2001

American Pharmaceutical Partners, Inc.
Attention: Tom Stothoff
2045 North Cornell Avenue
Melrose Park, IL 60160

Dear Sir:

This is in reference to your abbreviated new drug application dated July 28, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Milrinone Lactate Injection, 1 mg (base)/mL, packaged in 10 mg (base)/10 mL, 20 mg (base)/20 mL, and 50 mg (base)/50 mL single-dose vials.

Reference is also made to your amendment dated September 11, 2001.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product. The determination is subject to change on the basis of new information that may come to our attention.

The reference listed drug product (RLD) upon which you have based your application, Primacor® Injection of Sanofi Synthelabo, Inc. (Sanofi), is currently subject to a period of patent protection (U.S. Patent No.4,313,951, the "951" patent). Your application contains a Paragraph III Certification to the patent under Section 505(j)(2) (A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of this patent. As noted in the current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations", the "Orange book", the '951 patent was to expire

on November 26, 2001. However, the expiration of this patent has effectively been extended by an additional 6 months of marketing exclusivity under Section 111 of Title I of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The Modernization Act created section 505(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505(A) permits certain applications to obtain an additional six months of marketing exclusivity (pediatric exclusivity) if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population. Sanofi has submitted such information to the agency. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the '951 patent has expired, i.e., currently May 26, 2002.

In order to reactivate your application prior to final approval, please submit an amendment between 60 to 90 days prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. This submission should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above.

Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

Please note that this drug product may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to May 26, 2002, you should amend your application accordingly.

For further information on the status of this application or prior to submitting the minor amendment, please contact Stanley Shepperson, Pharm.D., Project Manager, at 301-827-5849.

Sincerely yours,

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

