CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

64084

APPROVAL LETTER

AADA 64-084

JUN 3 1996

Pharmacia Inc.
Attention: Frederick L. Grab
P.O. Box 16529
Columbus, OH 43216-6529

Dear Sir:

This is in reference to your abbreviated antibiotic application dated March 24, 1993, submitted pursuant to Section 507 of the Federal Food, Drug, and Cosmetic Act, for Sterile Bleomycin Sulfate USP, 15 and 30 units/vial.

Reference is also made to your amendments dated April 4 and May 20, 1996.

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 Sterile Bleomycin Sulfate, USP to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Blenoxane® of Bristol Laboratories, Inc.).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/ 6/3/96

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: AADA 64-084
DUP/Division File
HFD-600/RF
HFD-82
Field Copy

Endorsements:
HFD-643/SRosencrance/4/22/96; 5/6/96; as revised 5/22/96.
HFD-643/JHarrison/4/23/96; 5/6/96
HFD-617/RWest/4/29/96; 5/22/96
HFD-613/A.Payne 4/29/96; 5/3/96
HFD-613/J.Grace 4/29/96; 5/3/96
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F/T byRLWest:5/22/96

APPROVAL

For additional signatures see next page.