

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20939

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Roeper

NDA 20-939

Food and Drug Administration
Rockville MD 20857

JAN 28 2000

Biovail Laboratories Incorporated
c/o Keller and Heckman
Attention: Mr. John Dubeck
1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001

Dear Mr. Dubeck:

Please refer to your new drug application (NDA) dated November 5, 1997, received November 20, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diltiazem Hydrochloride Extended-release Capsules.

We acknowledge receipt of your submissions dated November 29 and December 6 and 17, 1999, and January 4, 2000. Your submission of January 4, 2000 constituted a complete response to our December 10, 1999 action letter.

This new drug application provides for the use of Diltiazem Hydrochloride Extended-release Capsules for the treatment of hypertension.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert and immediate container and carton labels in submission of January 4, 2000). Accordingly, the application is approved effective on the date of this letter.

We note that the approved dissolution specifications and method are as follows:

Method: USP Apparatus 1 (basket), 100 rpm, 900 mL of water at 37°C

Specifications: \int

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please note, if you choose to use a proprietary name for this product, the name and its use in the label must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call David Roeder, Regulatory Health Project Manager, at (301) 594-5300.

Sincerely,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research