



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-027/S-019

Biovail Laboratories, Inc.
Attention: Mr. Stefan Olchaski
700 Route 202-206 North
Bridgewater, NJ 08807-0980

Dear Mr. Olchaski:

Please refer to your supplemental new drug application dated December 21, 1998 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cardizem (diltiazem hydrochloride) 2.5 mg/5 ml and 50 mg/10 ml vial Injectable/Lyo-ject.

We acknowledge receipt of your submissions dated March 24, November 3, and December 10, 2004. Your submission of November 3, 2004 constituted a complete response to our June 24, 1999 approvable letter.

We have completed our review of this application, as amended and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the package insert submitted November 3, 2004.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-027/S-019." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Ms. Denise Hinton
Regulatory Project Manager
(301) 594-5333

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:

Mr. John Dubeck
Agent for Biovail Laboratories Incorporated
Keller and Heckman
1001 G Street, N.W. Suite 500 West
Washington D.C. 20001

**This is a representation of an electronic record that was signed electronically and
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/s/

Norman Stockbridge
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