



NDA 21-392/S-002

Biovail Technologies Limited
Attention: Mr. Stefan Olchaski
700 Route 202-206 North
Bridgewater, New Jersey 08807-0980

Dear Mr. Olchaski:

Please refer to your new drug application (NDA) dated June 6, 2003, submitted under section 505 (b) (1) of the Federal Food, Drug, and Cosmetic Act for Cardizem LA (diltiazem hydrochloride) 120, 180, 240, 300, 360 and 420 mg Extended Release Tablets.

We acknowledge receipt of your submissions dated June 12, August 21 (two), September 5, 2003, February 23 and March 10, 2004.

This supplemental new drug application provides for the use of Cardizem LA (diltiazem hydrochloride) 120, 180, 240, 300, 360 and 420 mg for the management of chronic stable angina.

We have completed our review of this application, as amended. This application 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 enclosed labeling (package insert) submitted March 10, 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 21-392/S-002." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Cardio-Renal Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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 M. Hinton
Regulatory Project Manager
(301) 594-5333

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

Enclosure (Draft labeling)

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Doug Throckmorton
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