DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-401/S-034

Biovail Techologies Ltd.
On Behalf of Biovail Laboratories International SRL
Attention: Naushad Islam, MS, R.Ph
Director, Regulatory Affairs
700 Route 202/206 North
Bridgewater, NJ 08807

Dear Mr. Islam:

Please refer to your supplemental new drug application dated December 20, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tiazac (diltiazem hydrochloride) 120, 180, 240, 300, 360, and 420 mg Extended-Release Capsules.

This "Changes Being Effected" supplemental new drug application provides for revisions to the labeling for Tiazac. Revisions were made to the **PRECAUTIONS, Drug Interactions** subsection of the labeling to add information regarding buspirone and quinidine so as to provide adequate information for the safe and effective use of the drug.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the electronic agreed-upon labeling text and with the minor editorial revisions listed below.

> Under the **PRECAUTIONS** section, please add hyphens to the following subsections as identified below:
>
> **Buspirone**, 5.5-fold and C_{max} 4.1-fold, **Benzodiazepines**, (3- to 4-fold) and (1.5- to 2.5-fold), **Lovastatin**, please change from 3-4 times to 3-to 4-fold and **Pregnancy**, 60-kg patient.

The final printed labeling (FPL) must be otherwise identical to the package insert submitted electronically on December 20, 2006.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-401/S-034**." 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 M. Hinton, Regulatory Project Manager, at (301) 796-1090.

Sincerely,

{See appended electronic signature page}

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

cc: Keller and Heckman LLP
Attention: Mr. John B. Heckman, U.S. Agent
1001 G Street, N.W., Suite 500W
Washington, DC 20001

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

/s/

Norman Stockbridge

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