DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-268/S-006

Biovail Technologies Ltd.
Attention: John B. Dubeck
Keller and Heckman
1001 G Street, N.W., Suite 500-W
Washington DC 20001

Dear Mr. Dubeck:

Please refer to your supplemental new drug application dated May 14, 2003, received May 15, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Teveten HCT (eprosartan mesylate and hydrochlorothiazide) Tablets, 600 mg/12.5 mg and 600 mg/25 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for (b)(4)----------, as an(b)(4)----------e for Teveten HCT Tablets.

We have completed our review of this supplemental application and it is approved.

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

If you have any question, please call Edward Fromm, Regulatory Health Project Manager, at (301) 594-5332.

Sincerely,

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar
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