DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-998/S-063

Biovail Technologies Ltd.
Attention: Wayne Kreppner, M. Sc.
3701 Concorde Parkway
Chantilly, Virginia 20151

Dear Mr. Kreppner:

Please refer to your supplemental new drug application dated February 28, 2002, received March 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vasotec™ Tablets 2.5 mg, 5 mg, 10 mg and 20 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for Merck Frosst in Kirkland, Quebec as a alternate manufacturing/testing/packaging site for the 2.5 mg, 5 mg, 10 mg and 20 mg strengths of Vasotec™ Tablets.

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

Please submit final printed labeling (FPL) for Vasotec™ Tablets identical to the submitted draft labeling in your next annual report.

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 Ms. Sandra L. Birdsong, Regulatory Health Project Manager, at (301) 594-5312.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Kasturi Srinivasachar

8/30/02 03:29:25 PM