DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-794/S-035

Biovail Laboratories International SRL
c/o Keller and Heckman LLP
Attention: John Dubeck
1001 G Street N.W.
Suite 500 West
Washington, DC 20001

Dear Mr. Dubeck:

Please refer to your supplemental new drug application, NDA 17-794/S-035, dated September 6, received September 9, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ativan (lorazepam) 0.5 mg, 1 mg, and 2 mg tablets.

This supplement, submitted under "Changes Being Effected", provides for revisions to labeling under the **CONTRAINDICATIONS**, **WARNINGS**, **PRECAUTIONS**, **ADVERSE REACTIONS**, **OVERDOSAGE**, and storage information. We note that these labeling changes are based on articles from the medial literature, spontaneous reports of adverse events since market introduction, and other medical information.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

Additionally. we note your agreement to the attached labeling in electronic communications between Dr. Lidia Mostovy, of Biovail, and CAPT Paul David, of this Agency, dated March 14, and 15, 2007.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 LCDR William Bender, Senior Regulatory Project Manager, at 301-796-0877.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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

/s/

Thomas Laughren
4/18/2007 09:11:02 AM