DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-140/S-028

Baxter Healthcare Corporation
Anesthesia & Critical Care
Attention: Frances Cacchio
Manager, Regulatory Affairs
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

Dear Mr. Cacchio:

We refer to your supplemental new drug application dated November 8, 2002, for Ativan (lorazepam) 2 mg/ml and 4 mg/ml Injection.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **PRECAUTIONS-Pediatric Use-General** section to include language regarding a "gasping syndrome" due to the preservative benzyl alcohol.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 8, 2002.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 CAPT Paul David, Chief Project Management Staff, at (301) 796-1058.

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

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