DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 14-879/S-044

Baxter Healthcare Corporation
Route 120 and Wilson Road
RLT-10
Round Lake, IL 60073-0490

Attention: Laura Cooper
Manager, Drug Regulatory Affairs

Dear Ms. Cooper:

Please refer to your supplemental new drug application dated September 16, 2004, received September 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dopram Injection (doxapram hyrochloride injection, USP).

We acknowledge receipt of your submission dated December 22, 2004.

This "Changes Being Effected" supplemental new drug application provides removal of latex warning statements throughout the package inserts and components.

We have completed our review of this supplemental new drug application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling submitted on December 22, 2004.

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 14-879/S-044**." Approval of this submission by FDA is not required before the labeling is used.

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

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Alison Meyer, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Division Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
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/

Bob Rappaport

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