DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 14-879/S-040

Baxter Healthcare Corporation Anesthesia & Critical Care
95 Spring Street
New Providence, NJ 07974

Attention: Laura Cooper
Manager, Drug Regulatory Affairs

Dear Ms. Cooper:

Please refer to your supplemental new drug application dated December 20, 2002, received December 23, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dopram® Injection, 20 mg/mL (doxapram hydrochloride injection, USP).

We acknowledge receipt of your submissions dated September 30 and October 14, 2003, and March 18, 2004.

Your submission dated October 14, 2003, constituted a complete response to our January 23, 2003, action letter.

This supplemental new drug application provides for revised **DESCRIPTION, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE, DOSAGE AND ADMINISTRATION,** and **HOW SUPPLIED** sections of the package insert, and revised carton, container and box labels.

We have completed our review of this application, as amended, and it is approved effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert and labeling text for the immediate container, carton, and box, submitted on March 18, 2004. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and (an) unapproved new drug.

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 NDA 14-879/S-040**." Approval of this submission by FDA is not required before the labeling is used.

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 Lisa E. Basham-Cruz, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

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

Bob Rappaport

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