DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-565/S-014

Baxter Healthcare Corporation
Anesthesia and Critical Care
2 Esterbrook Lane
Cherry Hill, NJ 08003

Attention: Nataliya Budnik
Coordinator, Regulatory Affairs

Dear Ms. Budnik:

Please refer to your supplemental new drug application dated December 3, 2004, received December 6, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duramorph (morphine sulfate injection, USP) and Infumorph (preservative-free morphine sulfate sterile solution).

This "Changes Being Effected" supplemental new drug application provides for changes to the CONTRAINDICATIONS and ADVERSE REACTIONS section of the Duramorph (morphine sulfate injection, USP) package insert.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert) submitted December 3, 2004 (copy enclosed).

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 18-565/S-014**." 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 submit 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 Lisa Basham-Cruz, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology 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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