DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-565/S-012

Baxter healthcare Corporation
Anesthesia and Critical Care
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

Attention: Nataliya Budnik
Coordinator, Regulatory Affairs

Dear Ms. Budnik:

Please refer to your supplemental new drug application dated December 5, 2003, received December 8, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duramorph (morphine sulfate injection) and Infumorph (preservative-free morphine sulfate sterile solution).

This "Changes Being Effected" supplemental new drug application provides for revised **WARNINGS** and **ADVERSE REACTIONS** sections of the Infumorph (preservative-free morphine sulfate sterile solution) package Insert.

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

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Lisa Basham-Cruz, Regulatory Project Manager, at (301) 827-7410.

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

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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