



NDA 18-565/S-010

Elkins-Sinn
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

Attention: Pamela J. Covin-Fogel
Senior Labeling Associate

Dear Ms. Covin-Fogel:

Please refer to your supplemental new drug application dated September 6, 2002, received September 9, 2002, 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).

Reference is also made to the June 19, 2003, telephone conversation between you and Ms. Parinda Jani of this Division.

This "Changes Being Effected" supplemental new drug application provides for revised immediate container and carton labels and **WARNINGS** and **OVERDOSAGE** sections of the package Insert.

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

As agreed to by you, the total milligrams per ampul volume and the mg/mL volume will be presented in equal prominence, including the font size and bolding, on all product labels, at each location the concentration is portrayed.

The changes may be reported in the annual report.

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

NDA 18-565/010

Page 2

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.
Acting 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
6/26/03 10:10:56 AM