DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-516/S-021

The Purdue Frederick Company
One Stamford Forum
Stamford, CT 06901-3431

Attention: Lawrence Winick
Director, US Regulatory Affairs

Dear Mr. Winick:

Please refer to your supplemental new drug application dated February 13, 2003, received February 14, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MS Contin® (morphine sulfate controlled-release) Tablets, 10, 30, 60, 100, and 200 mg.

This "Changes Being Effected" supplemental new drug application provides for changes to the ADVERSE REACTIONS and the HOW SUPPLIED sections of the package insert.

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

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted February 13, 2003).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-516/S-021." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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 Lisa E. Basham-Cruz, Regulatory Project Manager, at (301) 872-7420.

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
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