



NDA 19-516/S-019

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

Attention: James A. Webb
Assistant Director, Regulatory Affairs, CMC

Dear Mr. Webb:

Please refer to your supplemental new drug application dated August 26, 2002, received August 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MS Contin® (morphine sulfate controlled-release) 15, 30, 60, 100, and 200 mg Tablets.

We acknowledge receipt of your submission dated December 12, 2002.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of an alternate bottle count (120-count tablet fill) for all strengths.

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

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted December 13, 2002, and immediate container and carton labels submitted August 26, 2002).

Please submit the FPL electronically 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, 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. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-516/S-019." 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).

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If you have any questions, call Lisa Basham-Cruz, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

Dale Koble, Ph.D.
Chemistry Team Leader
Division of Anesthetic, Critical Care, and
Addiction Drug Products
DNDC II, Office of New Drug Chemistry

**This is a representation of an electronic record that was signed electronically and
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/s/

Dale Koble
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