



NDA 16-964/S-061

Hospira, Inc.  
275 North Field Drive  
Dept. 0389, Bldg. H2  
Lake Forest, IL 60045

Attention: Timothy Farber  
Sr. Specialist, Global Regulatory Affairs

Dear Mr. Farber:

Please refer to your supplemental new drug application dated April 7, 2005, received April 8, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Marcaine® (Bupivacaine Hydrochloride Injection, USP), and Marcaine® with Epinephrine 1:200,000 (as bitartrate)(Bupivacaine Hydrochloride and Epinephrine Injection, USP).

We acknowledge receipt of your submission dated October 6, 2005.

This “Changes Being Effected” supplemental new drug application provides for an addition of a sulfite warning statement to the immediate container closure and carton labels.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels).

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 16-964/S-061.**" 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 Allison Meyer, Regulatory Project Manager, at (301) 796-1258.

Sincerely,

*{See appended electronic signature page}*

Bob Rappaport, MD  
Director  
Division of Anesthesia, Analgesia and  
Rheumatology Product  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure

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

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Bob Rappaport  
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