



NDA 016964/S-070  
NDA 018692/S-015  
NDA 022046/S-004

**SUPPLEMENT APPROVAL**

Hospira, Inc.  
275 North Field Drive  
Dept. 0389, Bldg. H2-2  
Lake Forest, IL 60045

Attention: Hollie Miller  
Associate, Regulatory Affairs

Dear Ms. Miller:

Please refer to your Supplemental New Drug Applications (sNDAs) dated August 19, 2011, received August 19, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following products.

NDA #	Supplement #	Product
016964	070	Marcaine and Marcaine with Epinephrine Injection
018692	015	Marcaine Spinal Injection
022046	004	Bupivacaine hydrochloride and epinephrine bitartrate injection,

We acknowledge receipt of your amendments dated December 16, 2011.

These “Prior Approval” supplemental new drug applications provide for changes to the **Carcinogenesis, Mutagenesis, Impairment of Fertility**, and **Pregnancy Category** subsections of the **PRECAUTIONS** section of the package inserts.

We have completed our review of these supplemental applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text for each product.

We note that your December 16, 2011, submission for each product includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Allison Meyer, Regulatory Project Manager, at (301) 796-1258.

Sincerely,

*{See appended electronic signature page}*

Bob A. Rappaport, MD  
Director  
Division of Anesthesia, Analgesia,  
and Addiction Drugs  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

ENCLOSURE(S): Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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BOB A RAPPAPORT  
01/30/2012