DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-046/S-001

Hospira, Inc.
275 North Field Drive
Dept. 389, Bldg. H2-2
Lake Forest, IL 60045

Attention: Christopher Leintz
Manager, Global Regulatory Affairs

Dear Mr. Leintz:

Please refer to your supplemental new drug application dated February 28, 2006, received March 1, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Marcaine® with Epinephrine 1:200,000 (as Bitartrate) (Bupivacaine HCl and Epinephrine Injection, USP) for Dental Use.

We acknowledge receipt of your submission dated August 9 and August 28, 2006.

This "Changes Being Effected" supplemental new drug application provides for a change in name to Bupivacaine HCl for the Dental Use product.

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.

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

Enclosure

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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