Hospira

0458 8 MAY -7 A9:25

Submission Date: MAY 06 2008

Food and Drug Administration
Division of Dockets Management
Office of Management Programs
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket Number 2006P-0360/CP 1**
**Mepivacaine Hydrochloride Injection USP, 3%**

**WITHDRAWAL OF CITIZEN PETITION**

Reference is made to the above-referenced Citizen Petition (Document Number 2006P-0360/CP 1) submitted on August 25, 2006, requesting the FDA to determine that the discontinued formulation of Carbocaine® Injection, 3%, supplied in 1.8 mL dental cartridges, was not discontinued for safety and efficacy reasons. Reference is also made to the teleconference of April 29, 2008, between Ms. Nancy Boocker (FDA/CDER) and Ms. Melissa Nguyen (Hospira). As per the Agency's recommendation, Hospira hereby withdraws the above-referenced Citizen Petition (Document Number 2006P-0360/CP 1) submitted on August 25, 2006, since the Agency had announced its determination that the reference listed drug (RLD), Carbocaine® Injection, 3%, supplied in 1.8 mL dental cartridges, was not withdrawn from sale for reasons of safety or effectiveness in the Federal Register dated April 28, 2008 (Volume 73, no. 82).

Sincerely,

HOSPIRA, INC.

5-5-2008

Melissa A. Nguyen
Manager, Regulatory Affairs
Phone: (620) 241-6200, Ext. 6315
Fax: (224) 212-5401
Email: melissa.nguyen@secure.hospira.com

FDA-2006-P-0269

C

Hospira Inc.
275 North Field Drive
Dept. 389, Bldg. H2-2
Lake Forest, IL 60064

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

# APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

*(Title 21, Code of Federal Regulations, Parts 314 & 601)*

*Form Approved: OMB No. 0910-0338*
*Expiration Date: September 30, 2008*
*See OMB Statement on page 2.*

**FOR FDA USE ONLY**

APPLICATION NUMBER

## APPLICANT INFORMATION

| NAME OF APPLICANT | DATE OF SUBMISSION |
|---|---|
| Hospira, Inc. | MAY 06 2008 |
| **TELEPHONE NO.** *(Include Area Code)* | **FACSIMILE** *(FAX)* **Number** *(Include Area Code)* |
| (620) 241-6200, Ext. 6315 | 224-212-5401 |
| **APPLICANT ADDRESS** *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):* | **AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE |
| 275 N. Field Drive<br>Dept. 0389, Bldg. H2<br>Lake Forest, IL 60045-5046 | |

## PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 40-806

| ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)* | PROPRIETARY NAME *(trade name)* IF ANY |
|---|---|
| Mepivacaine Hydrochloride Injection USP | |

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*
2-Piperidinecarboxamide, N-(2-6-dimethylphenyl)-1-methyl,monohydrochloride

CODE NAME *(If any)*

| DOSAGE FORM: | STRENGTHS: | ROUTE OF ADMINISTRATION: |
|---|---|---|
| Injectable | 3% (30 mg/mL) | Injection |

(PROPOSED) INDICATION(S) FOR USE:
Indicated for production of local anesthesia for dental procedures by infiltration or nerve block in adults and pediatric patients.

## APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)*
☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug Carbocaine Holder of Approved Application Eastman Kodak Company

TYPE OF SUBMISSION *(check one)*
☐ ORIGINAL APPLICATION ☐ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☒ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
Withdrawal of Citizen Petition submitted on 8/25/2006 (Document # 2006P-0360/CP 1)

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED N/A THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

**ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)**
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

N/A

**Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)**

DMF 4936, Cambrex (Mepivacaine Hydrochloride USP); DMF 1546, West (4432/50 Gray and West 4405/50 Gray plungers and 8-I seals); DMF 854, Hospira (Ashland 5366 Gray plungers); DMF 9543, Kimble (Tubing glass cartridges); DMF 3469, Orgamol (Mepivacaine Hydrochloride USP) - Pending

| This application contains the following items: *(Check all that apply)* | |
|---|---|
| ☐ | 1. Index |
| ☐ | 2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling |
| ☐ | 3. Summary (21 CFR 314.50 (c)) |
| ☒ | 4. Chemistry section |
| ☒ | A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2) |
| ☐ | B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request) |
| ☐ | C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2) |
| ☐ | 5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2) |
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| ☐ | 7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4)) |
| ☐ | 8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2) |
| ☐ | 9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2) |
| ☐ | 10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2) |
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| ☐ | 12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2) |
| ☐ | 13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c)) |
| ☐ | 14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A)) |
| ☐ | 15. Establishment description (21 CFR Part 600, if applicable) |
| ☐ | 16. Debarment certification (FD&C Act 306 (k)(1)) |
| ☐ | 17. Field copy certification (21 CFR 314.50 (l)(3)) |
| ☐ | 18. User Fee Cover Sheet (Form FDA 3397) |
| ☐ | 19. Financial Information (21 CFR Part 54) |
| ☐ | 20. OTHER *(Specify)* |

**CERTIFICATION**

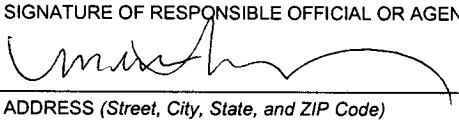
I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

**Warning:** A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

| SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT | TYPED NAME AND TITLE | DATE: |
|---|---|---|
|  | Melissa A. Nguyen<br>Manager, Regulatory Affairs | 5-5-2008 |

| ADDRESS *(Street, City, State, and ZIP Code)* | Telephone Number |
|---|---|
| 275 North Field Drive, Lake Forest, IL 60045-5046 | (620) 241-6200, Ext. 6315 |

**Public reporting burden for this collection of information** is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
Food and Drug Administration

# Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

## SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Hospira, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
MAY 06 2008

3. ADDRESS *(Number, Street, State, and ZIP Code)*
275 N. Field Drive
Dept. 0389, Bldg. H2-2
Lake Forest, IL 60045-5046

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 620-241-6200, Ext. 6315
(Fax) 224-212-5401

## PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
**FOR DEVICES:** Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
*(Attach extra pages as necessary)*

Mepivacaine Hydrochloride Injection USP

2-Piperidinecarboxamide, N-(2-6-dimethylphenyl)-1-methyl, monohydrochloride

## APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☒ ANDA ☐ BLA ☐ PMA ☐ HDE ☐ 510(k) ☐ PDP ☒ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*
40-806 2006P-0360/CP 1

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

## CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

**The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.**
**Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Melissa A. Nguyen
(Title) Manager, Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
275 N. Field Drive
Dept. 0389, Bldg. H2-2
Lake Forest, IL 60045-5046

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 620-241-6200, Ext. 6315
(Fax) 224-212-5401

15. DATE OF CERTIFICATION
5-5-2008



PSC Graphics: (301) 443-1090 EF

Hospira

Submission Date: MAY 0 6 2008

Food and Drug Administration
Division of Dockets Management
Office of Management Programs
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket Number 2006P-0360/CP 1**
**Mepivacaine Hydrochloride Injection USP, 3%**

**WITHDRAWAL OF CITIZEN PETITION**

Reference is made to the above-referenced Citizen Petition (Document Number 2006P-0360/CP 1) submitted on August 25, 2006, requesting the FDA to determine that the discontinued formulation of Carbocaine® Injection, 3%, supplied in 1.8 mL dental cartridges, was not discontinued for safety and efficacy reasons. Reference is also made to the teleconference of April 29, 2008, between Ms. Nancy Boocker (FDA/CDER) and Ms. Melissa Nguyen (Hospira). As per the Agency's recommendation, Hospira hereby withdraws the above-referenced Citizen Petition (Document Number 2006P-0360/CP 1) submitted on August 25, 2006, since the Agency had announced its determination that the reference listed drug (RLD), Carbocaine® Injection, 3%, supplied in 1.8 mL dental cartridges, was not withdrawn from sale for reasons of safety or effectiveness in the Federal Register dated April 28, 2008 (Volume 73, no. 82).

Sincerely,

HOSPIRA, INC.

5-5-2008

Melissa A. Nguyen
Manager, Regulatory Affairs
Phone: (620) 241-6200, Ext. 6315
Fax: (224) 212-5401
Email: melissa.nguyen@secure.hospira.com

Hospira Inc.
275 North Field Drive
Dept. 389, Bldg. H2-2
Lake Forest, IL 60064

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

# APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

*(Title 21, Code of Federal Regulations, Parts 314 & 601)*

*Form Approved: OMB No. 0910-0338*
*Expiration Date: September 30, 2008*
*See OMB Statement on page 2.*

**FOR FDA USE ONLY**

APPLICATION NUMBER

## APPLICANT INFORMATION

| NAME OF APPLICANT | DATE OF SUBMISSION |
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| Hospira, Inc. | MAY 06 2008 |
| TELEPHONE NO. *(Include Area Code)* | FACSIMILE *(FAX)* Number *(Include Area Code)* |
| (620) 241-6200, Ext. 6315 | 224-212-5401 |
| APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*: 275 N. Field Drive, Dept. 0389, Bldg. H2, Lake Forest, IL 60045-5046 | AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE |

## PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 40-806

| ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)* | PROPRIETARY NAME *(trade name)* IF ANY |
|---|---|
| Mepivacaine Hydrochloride Injection USP | |

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*: 2-Piperidinecarboxamide, N-(2-6-dimethylphenyl)-1-methyl,monohydrochloride

CODE NAME *(If any)*:

| DOSAGE FORM: | STRENGTHS: | ROUTE OF ADMINISTRATION: |
|---|---|---|
| Injectable | 3% (30 mg/mL) | Injection |

(PROPOSED) INDICATION(S) FOR USE:
Indicated for production of local anesthesia for dental procedures by infiltration or nerve block in adults and pediatric patients.

## APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)* ☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) ☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug: Carbocaine — Holder of Approved Application: Eastman Kodak Company

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION ☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☒ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
Withdrawal of Citizen Petition submitted on 8/25/2006 (Document # 2006P-0360/CP 1)

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED: N/A — THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

**ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)**
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**CERTIFICATION**

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3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
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5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

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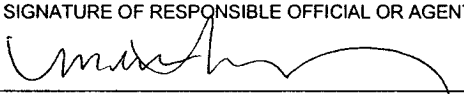
| SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT | TYPED NAME AND TITLE | DATE: |
|---|---|---|
|  | Melissa A. Nguyen<br>Manager, Regulatory Affairs | 5-5-2008 |

| ADDRESS *(Street, City, State, and ZIP Code)* | Telephone Number |
|---|---|
| 275 North Field Drive, Lake Forest, IL 60045-5046 | (620) 241-6200, Ext. 6315 |

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Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

## SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Hospira, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
MAY 06 2008

3. ADDRESS *(Number, Street, State, and ZIP Code)*
275 N. Field Drive
Dept. 0389, Bldg. H2-2
Lake Forest, IL 60045-5046

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 620-241-6200, Ext. 6315
(Fax) 224-212-5401

## PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
**FOR DEVICES:** Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
*(Attach extra pages as necessary)*

Mepivacaine Hydrochloride Injection USP

2-Piperidinecarboxamide, N-(2-6-dimethylphenyl)-1-methyl, monohydrochloride

## APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☒ ANDA ☐ BLA ☐ PMA ☐ HDE ☐ 510(k) ☐ PDP ☒ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*
40-806 2006P-0360/CP 1

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

## CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. **Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Melissa A. Nguyen
(Title) Manager, Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
275 N. Field Drive
Dept. 0389, Bldg. H2-2
Lake Forest, IL 60045-5046

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 620-241-6200, Ext. 6315
(Fax) 224-212-5401

15. DATE OF CERTIFICATION
5-5-2008



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**Lake Forest, IL 60045**

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