DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-486

Empi, Inc.
C/O Gary L. Yingling
Kirkpatrick & Lockhart, LLP
1800 Massachusetts Avenue NW
Suite 200
Washington, DC 20036-1221

Dear Mr. Yingling:

Please refer to your new drug application (NDA) dated and received, September 26, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for TRADENAME (Lidocaine HCl 2% and Epinephrine 1:100,000 Solution for Topical Iontophoretic System).

We acknowledge receipt of your submissions dated February 8, March 13, April 13, October 15, and December 11, 2002, July 29 and September 26, 2003, January 21, February 3, March 16, April 1, May 21, June 7, 11, 23, and 30, August 16, September 3, 10, and 17, and October 1, 11, 13, 19 and 26, 2004.

This new drug application provides for the use of TRADENAME (Lidocaine HCl 2% and Epinephrine 1:100,000 Solution for Topical Iontophoretic System) for the iontophoretic production of local analgesia for superficial dermatological procedures such as venipuncture, shave removals and punch biopsies.

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 (text for the package insert and immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidances for industry titled *Providing Regulatory Submissions in Electronic Format – NDA* and *Providing Regulatory Submissions in Electronic Format-Content of Labeling*. Alternatively, except for the content of labeling, which must be submitted electronically in PDF format, 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 NDA 21-486**." Approval of this submission by FDA is not required before the labeling is used.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation. Additionally, we remind you of your agreement to revise the established name pending the Agency's further recommendations based upon discussion with the United States Pharmacopeia (USP).

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for ages six to seventeen and newborn to five years until October, 2008 and October, 2011, respectively.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1. Deferred pediatric study under PREA for the iontophoretic production of local analgesia for superficial dermatological procedures in pediatric patients ages 6 - 17 years.

   Evaluate the safety and efficacy of (Lidocaine HCl 2% and Epinephrine 1:100,000 Solution for Topical Iontophoretic System) when used on pediatric patients ages six through seventeen years across a variety of dermatological procedures. This study should include dose ranging in all age groups to discern differences from adult dosing requirements and to identify a dose which is safest and most efficacious for the procedures evaluated. If more than one delivery electrode patch could be required for a given procedure, dose ranging should be conducted for each electrode identified as appropriate for the condition treated.

Protocol Submission:	by June 2005
Study Start:	by December 2005
Final Report Submission:	by October 2008

2. Deferred pediatric study under PREA for the iontophoretic production of local analgesia for superficial dermatological procedures in pediatric patients ages newborn through five years.

   Evaluate the safety and efficacy of (Lidocaine HCl 2% and Epinephrine 1:100,000 Solution for Topical Iontophoretic System) when used on pediatric patients ages newborn through five years across a variety of dermatological procedures. This study should include dose ranging in all age groups to discern any differences in dosing requirements compared to older pediatric patients and to identify a dose which is safest and most efficacious for the procedures evaluated. If more than one delivery electrode

patch could be required for a given procedure, dose ranging should be conducted for each electrode identified as appropriate for the condition treated.

Protocol Submission:	by October 2007
Study Start:	by April 2008
Final Report Submission:	by October 2011

Submit final study reports to this NDA. For administrative purposes, all submissions related to these pediatric postmarketing study commitments must be clearly designated "**Required Pediatric Study Commitments**".

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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 Lisa Malandro, Regulatory Project Manager, at (301) 827-7416.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Division Director
Division of Anesthetic, Critical Care
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
Package insert
Immediate carton and container labeling

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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