DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 079138

Hospira Inc.
Attention: Kimberly Ritenour-Rodgers
Sr. Associate, Regulatory Affairs
Dept. 0389, Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045-5046

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated July 25, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Articaine Hydrochloride 4% and Epinephrine 1:100,000 Injection (Dental Cartridge).

Reference is also made to your amendments dated March 7, June 11, June 16, and September 16, 2008; February 12, and November 10, 2009; and February 12, April 26, and May 5, 2010.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Articaine Hydrochloride 4% and Epinephrine 1:100,000 Injection to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Septocaine 4% with Epinephrine Injection 1:100,000, of Deproco Inc.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling. For administrative purposes, please designate this submission as "***LABELING/SPL FINAL for Approved ANDA 079138***".

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-79138	ORIG-1	HOSPIRA INC	ARTICAINE HYDROCHLORIDE WITH EPINEPHRINE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST
06/18/2010
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.