DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020971/S-023

SUPPLEMENT APPROVAL

Deproco, Inc.
c/o Arent Fox LLP
1050 Connecticut Avenue, NW
Washington, DC 20036

Attention: Wayne H. Matelski
Counsel and Official Correspondent

Dear Mr. Matelski:

Please refer to your Supplemental New Drug Application (sNDA) dated May 4, 2010, received May 5, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Septocaine (articaine HCl and epinephrine) Injection, [articaine hydrochloride 4% and 1:200,000 epinephrine, and articaine hydrochloride 4% and 1:100,000 epinephrine].

We acknowledge receipt of your amendment dated October 18, 2010.

This "Prior Approval" supplemental new drug application provides for updates to the carton and container labeling to reflect recent changes in the package insert for your product.

We have completed our review of this supplemental application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon carton and container labeling.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels, except for the revision listed below, as soon as they are available, but no more than 30 days after they are printed.

> Add the barcode to the cartridge label for the product made in Canada (per the agreement in your October 18, 2010, amendment).

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA020971/S-023**." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Kimberly Compton, R.Ph., Regulatory Project Manager, at (301) 301-796-1191.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia and Analgesia Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
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/

RIGOBERTO A ROCA on behalf of BOB A RAPPAPORT
11/12/2010