DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

N 20-971/S-007

Deproco, Inc.
c/o Arent Fox
1050 Connecticut Ave N.W.
Washington, DC 20036-5339

Attention: Wayne H. Matelski
U.S. Representative and Agent

Dear Mr. Matelski:

Please refer to your supplemental new drug application dated April 13, 2004, received April 14, 2004, submitted under section 505(b) pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Septocaine (articaine HCl 4% with epinephrine 1:100,000) Injection.

We also acknowledge receipt of your submissions dated May 13, and July 23, 2004.

This "Changes Being Effected" supplemental new drug application proposes removal of the scale from the cartridge label in order to increase the size of other information that must appear on the label.

We have completed our review of this supplemental new drug application, as amended, and it is approved effective on the date of this letter for use as recommended in the final printed labeling (FPL) submitted on July 23, 2004.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions call, Kimberly Compton, Regulatory Project Manager, at (301) 827-7432.

Sincerely,

{See appended electronic signature page}

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

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

10/14/04 01:57:12 PM