DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-971/S-009

Arent Fox, PLLC
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5339

Attention: Wayne Matelski, Esq.
Counsel to and U.S. Agent for Deproco, Inc.

Dear Mr. Matelski:

Please refer to your supplemental new drug application dated August 4, 2004, received August 5, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Septocaine® (Articaine Hydrochloride 4% (40 mg/mL) with Epinephrine 1:100,000 Injection).

We acknowledge receipt of your submissions dated August 25, and September 1, 2004, and September 2, 2005.

This supplemental new drug application proposes to introduce a private-labeled version of the approved product under the trade name ZORCAINE.

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 and with the following minor editorial revisions agreed upon during the February 3, 2005, teleconference:

1. You will ensure that the established name on the Container and Carton labels is at least ½ the size of the proprietary name per the requirements of CFR 201.10(g)(2).

2. You will revise the Carton label to include net quantity of each vial.

3. You will decrease the prominence of the name "Cook-Waite" on the Carton label as it appears more prominent than the proprietary and established names.

4. You will consider adding a barcode to each vial.

The final printed labeling (FPL) must be identical to the submitted labeling (text for the package insert submitted September 1, 2004, immediate container and carton labels submitted September 1, 2004).

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 supplement NDA 20-971/S-009**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that current and future promotional materials should be revised to reflect the new approved name, Zorcaine. Furthermore, we advise you to implement the aforementioned revision in a manner that does not imply that Zorcaine is a newly approved product.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Allison Meyer, Regulatory Project Manager, at (301) 827-7431.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, MD
Director
Division of Anesthetic, Critical Care,
And Addiction Drug Products
Office of New Drugs 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

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