

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER  
20-971**

**Microbiology Review(s)**

**REVIEW FOR HFD-170  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF HFD-805**

OCT 28 1998

**Microbiologist's Review #2 of NDA 20-971  
Response to Information Request  
October 28, 1998**

- A. 1. **APPLICATION NUMBER:** 20-971
- APPLICANT:** Deproco Inc.  
245-C Quigley Blvd.  
New Castle, DE 19720
2. **PRODUCT NAMES:** Septanest — and Septanest i —
3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Septanest —  
(Articaine hydrochloride 4% with epinephrine 1/200,000 solution for injection)  
and Septanest i — (Articaine hydrochloride 4% with epinephrine 1/100,000  
solution for injection) in glass cartridges filled to a volume 1.7 ml.
4. **METHOD(S) OF STERILIZATION:** —
5. **PHARMACOLOGICAL CATEGORY:** Nerve block or infiltration
- B. 1. **DATE OF INITIAL SUBMISSION:** March 30, 1998
2. **AMENDMENT:**
3. **RELATED DOCUMENTS:** Response to Request for Additional  
Information, September 10, 1998.
4. **ASSIGNED FOR REVIEW:** October 5, 1998
5. **DATE OF CONSULT REQUEST:** October 5, 1998
- C. **REMARKS:**

The submission responds to questions presented to the Applicant as a result of Microbiologist's Review #1. The questions from the "List of Microbiology Deficiencies and Comments" have been copied into the "Review Notes" section of this review and the responses are individually reviewed.

**D. CONCLUSIONS:**

The answers in response to the microbiology deficiencies are satisfactory. The submission is recommended for approval on issues concerning microbiology.

13

10/28/98

**Brenda Uratani, Ph.D.**  
**Review Microbiologist**

JAC 10/28/98

cc:

NDA 20-971  
HFD-170/ Div. File  
HFD-805/ Uratani  
HFD-170/CSO/Nolan  
drafted by: Brenda Uratani, 10/28/98  
R/D initialed by P. Cooney, 10/28/98

Redacted

5

pages of trade

secret and/or

confidential

commercial

information

**REVIEW FOR HFD-170  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF HFD-805**

**Microbiologist's Review #1 of NDA 20-971  
July 30, 1998**

- A. 1. **APPLICATION NUMBER:** 20-971
- APPLICANT:** Deproco Inc.  
245-C Quigley Blvd.  
New Castle, DE 19720
2. **PRODUCT NAMES:** Septanest — and Septanest '—
3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Septanest —  
(Articaine hydrochloride 4% with epinephrine 1/200,000 solution for injection) and  
Septanest '— (Articaine hydrochloride 4% with epinephrine 1/100,000 solution for  
injection) in glass cartridges filled to a volume 1.7 ml.
4. **METHOD(S) OF STERILIZATION:** —
5. **PHARMACOLOGICAL CATEGORY:** Nerve block or infiltration
- B. 1. **DATE OF INITIAL SUBMISSION:** March 30, 1998
2. **AMENDMENT:** none
3. **RELATED DOCUMENTS:**
4. **ASSIGNED FOR REVIEW:** June 17, 1998
5. **DATE OF CONSULT REQUEST:** June 12, 1998
- C. **REMARKS:**

Septanest — and Septanest '— contain 4% articaine hydrochloride with 2 different strengths of epinephrine. The drug product is manufactured by Specialites Septodont in Paris, France.

**D. CONCLUSIONS:**

The submission does not contain sufficient information to assure the sterility and safety of the drug product. The NDA is, therefore, not recommended for approval as submitted. Specific comments are provided in "Review Notes" and in the "List of Microbiology Deficiencies and Comments".

**OFFICIAL**

Brenda Uratani, Ph.D.  
Review Microbiologist

cc:

NDA 20-971  
HFD-170/ Div. File  
HFD-805/ Uratani  
HFD-170/CSO/Nolan  
drafted by: Brenda Uratani, 7/30/98  
R/D initialed by P. Cooney, 7/30/98

Redacted 7

pages of trade

secret and/or

confidential

commercial

information