

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 20937**

**MICROBIOLOGY REVIEW(S)**

CULANSEN

**REVIEW FOR HFD-160  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF HFD-805**

Microbiologist's Review #1 of NDAs 20-937, 20-975, 20-976  
April 24, 1998

A. 1. **APPLICATION NUMBER:** 20-937 (glass vials),  
20-975 (Pharmacy Bulk Package),  
20-976 (plastic syringes).

**APPLICANT:** Mallinckrodt Inc.  
675 McDonnell Boulevard  
PO Box 5840  
St. Louis MO 63134

2. **PRODUCT NAMES:** Optimark (gadoversetamide injection)

3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Optimark Injection contains 330.9 mg/ml of gadoversetamide. It is to be administered intravenously.

4. **METHOD(S) OF STERILIZATION:** sterilization

5. **PHARMACOLOGICAL CATEGORY:** Optimark Injection is indicated for use with magnetic resonance imaging (MRI) in adults to provide contrast enhancement in lesions in the central nervous system and liver.

B. 1. **DATE OF INITIAL SUBMISSION:** February 28, 1998

2. **AMENDMENT:** none

3. **RELATED DOCUMENTS:**

4. **ASSIGNED FOR REVIEW:** March 13, 1998

5. **DATE OF CONSULT REQUEST:** March 9, 1998

C. **REMARKS:**

Optimark Injection is submitted as three separate NDAs: NDA 20-937, Optimark packaged in glass vials (10 ml vials containing 5 ml or 10 ml of solution, 20 ml vials containing 15 ml or 20 ml of solution); NDA 20-975, Optimark packaged as a

Pharmacy Bulk Package (50 ml); and NDA 20-976, Optimark packaged in plastic syringes (10, 15, 20, and 30 ml fill in a 10, 15, 20 and 30 ml syringe, respectively). The drug product is manufactured at the Mallinckrodt Medical Inc. Raleigh Parenteral facility in Raleigh, North Carolina.

**D. CONCLUSIONS:**

The sterilization data of the drug product for the NDA 20-937, 20-975 and 20-976 are adequate for sterility assurance. The submission is recommended for approval for issues concerning microbiology.

/S/  
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Review Microbiologist

4/24/98

JAC 4/29/98

cc:

NDA: 20-937, 20-975, 20-976

HFD-160/ Div. File

HFD-805/ Uratani

HFD-160/CSO/Colangelo

drafted by: Brenda Uratani, 4/24/98

R/D initialed by P. Cooney, 4/24/98