CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-923

Microbiology Review(s)

REVIEW FOR HFD-160
OFFICE OF NEW DRUG CHEMISTRY
DENTAL DRUG PRODUCTS
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW OF NDA 20-923
October 21, 1997

A. 1. NDA: 20-923

APPLICANT: Mallinckrodt Inc.
675 Mcdonnell Blvd.
St. Louis, MO 6313

2. PRODUCT NAME: Optiray Pharmacy Bull Package

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Pharmacy bulk package supplied in 200mL/250 mL glass containers for intravenous administration only after dispensing into final container. Rx

4. METHOD(S) OF STERILIZATION: sterilization

5. PHARMACOLOGICAL CATEGORY: Diagnostic x-ray contrast agent

6. DRUG PRIORITY CLASSIFICATION: 5C

B. 1. DATE OF INITIAL SUBMISSION: September 30, 1997

2. DATE OF AMENDMENT: N/A

3. RELATED DOCUMENTS: NDA 19-710 (Mallinckrodt)

4. ASSIGNED FOR REVIEW: October 3, 1997

C. REMARKS:

The NDA provides for a Pharamcy Bulk Package for the approved drug Optiray, NDA 19-710. The NDA 19-710 is currently approved for strengths of 160, 240, 300 ,320 and 350, all supplied in the 200mL/250 mL glass bottle. The subject NDA provides for the 240, 320 and 350 strengths in the same container fill/size. It is noted on page 28 of the submission that NDA 19-710 does not provide for Optiray 160 and Optiray 300 in the 200mL fill/250mL

bottle. Therefore, these concentrations are not currently proposed for the subject NDA.

The applicant confirms that the products are the same as those approved under the referenced NDA 19-710; manufacturing, packaging, testing and manufacturing site are unchanged. With the exception of the changes and modifications required for a Pharmacy Bulk Package, the labeling is the same. The applicant has also confirmed in a telephone conversation with Dr. Leutzinger(HFD-160, Chemistry Team Leader) that materials and sterilization procedures remain as approved for NDA 19-710. Since no changes have been made, the only microbiology/sterility assurance issue is the labeling providing for a Pharmacy Bulk Package. It is stated that the draft labeling has been revised to meet the requirements of the FDA Pharmacy Bulk Package Labeling Guideline. Samples of revised container labeling and package insert are submitted under Section 2. The draft container labeling and information in the product package insert have been revised in accordance with requirements contained in the FDA guideline.

CONCLUSIONS: The submission is recommended for approval of sterility assurance of the proposed Pharmacy Bulk Package.

/S/ 10/21/97
Vivian Greenman

/S/ 10/21/97

cc:
Orig.NDA 20-923
HFD 160/C.Ferre-Hockensmith.
drafted by: V. Greenman
R/D init. by PH Cooney
PC# ND20923.R1