CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-321

Microbiology Review(s)
CONSULTATIVE REVIEW FOR HFD-110
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
MICROBIOLOGIST'S REVIEW NO. 1 OF NDA 21-321
July 9, 2001

A. 1. NDA 21-321

APPLICANT: Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, IL 60085-6730

2. PRODUCT NAME: Extraneal™ (7.5% icodextrin) Peritoneal Dialysis Solution
Orphan Drug Designation (97-1056)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Sterile solution for intraperitoneal administration, supplied in 2000 mL and 3000 mL plastic ( ) containers (UltraBag or Ambu-Flex). Rx

4. METHOD OF STERILIZATION: sterilization

5. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPAL INDICATION: Treatment of chronic renal failure

6. DRUG PRIORITY CLASSIFICATION: 4S

B. 1. DATE OF INITIAL SUBMISSION:
Letter Date: December 22, 2001
Consult Request: January 2, 2001
Assigned for Review: January 22, 2001

2. AMENDMENTS: March 20, 2001
3. May 23, 2001

3. SUPPORTING DOCUMENTS:
NDA 20-163
NDA 17-512
NDA 20-183
DMF (Baxter Healthcare)
DMF

C. REMARKS:

The submission is an original NDA that provides for a new drug product solution supplied in two currently approved container configurations. The containers are identical to those currently marketed under NDAs 20-163 and 17-512.
The amendment of March 20, 2001 provides information and data requested by the reviewer in a telephone conversation held on February 1, 2001 between her and Ms. Rybicki of Baxter Healthcare. The amendment of May 23, 2001 responds to requests for additional information concerning sterilization of (T-Con of May 21, 2001 between Ms. Rybicki of Baxter and the reviewer).

D. CONCLUSIONS:

Recommend approval of the NDA for sterility assurance of the subject drug. See Review Notes.

_/S_

Vivian Greenman

cc:
Orig. NDA: 21-321
HFD 160/Consult File
Drafted by: V. Greenman, HFD-805
HFD-110, John Guzman
R/D init. By P.H. Cooney
PC# NDA21321Orig.R1
17 pages redacted from this section of the approval package consisted of draft labeling
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Vivian Greenman
7/12/01 12:22:52 PM
MICROBIOLOGIST

Peter Cooney
7/12/01 01:08:46 PM
MICROBIOLOGIST