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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.

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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

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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