

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020924

MICROBIOLOGY REVIEW(S)

McCoat

**REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805**

NOV -2 1998

Microbiologist's Review #1 of NDA 20-924
October 30, 1998

A. 1. **APPLICATION NUMBER:** 20-924

APPLICANT: Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

2. **PRODUCT NAMES:** Cernevit-12 IV Multivitamins

DOSAGE FORM AND ROUTE OF ADMINISTRATION: Lyophilized powder for reconstitution. Intravenous administration.

3. **METHOD(S) OF STERILIZATION:** 

4. **PHARMACOLOGICAL CATEGORY:** Daily multivitamin maintenance dosage for adults and children aged 11 years and above receiving total parenteral nutrition of in other situation where administration of multivitamins by the intravenous route is required.

B. 1. **DATE OF INITIAL SUBMISSION:** March 20, 1998

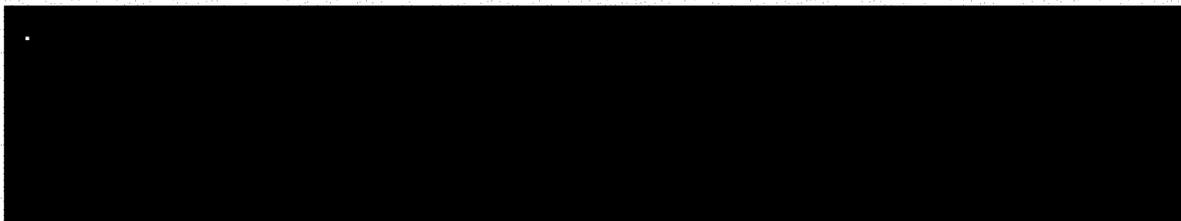
2. **AMENDMENT:** Minor Amendments (8/6/98, 8/27/98)

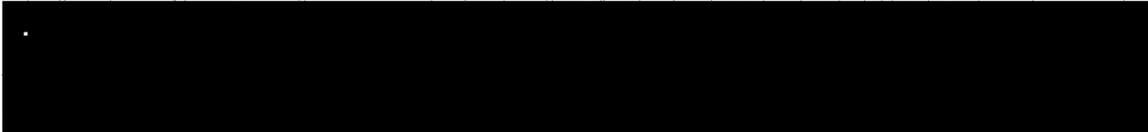
3. **RELATED DOCUMENTS:**

4. **ASSIGNED FOR REVIEW:** April 8, 1998

5. **DATE OF CONSULT REQUEST:** March 26, 1998

C. **REMARKS:**





D. CONCLUSIONS:

The submission is recommended for approval on issues concerning microbiology. However, a post-approval commitment should be made to submit specifications concerning holding period between the sterile filtration of the bulk drug product and its filling into the vials at [REDACTED]

/S/

[REDACTED]
Brenda Uratani, Ph.D.
Review Microbiologist

10/30/98

/S/

11/2/98

APPEARS THIS WAY ON ORIGINAL

cc:

NDA 20-924
HFD-510/ Div. File
HFD-805/ Uratani
HFD-510/McCort
drafted by: Brenda Uratani, 10/30/98
R/D initialed by P. Cooney, 10/30/98