

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020924

Trade Name: CERNEVIT-12

Generic Name: MULTIVITAMINS FOR INFUSION

Sponsor: BAXTER HEALTHCARE

Approval Date: 04/06/99

INDICATION(s): MULTIVITAMINS FOR INFUSION

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APPLICATION: 020924

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)	X			
Statistical Review(s)				X
Microbiology Review(s)	X			
Clinical Pharmacology	X			
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APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-924

Baxter Healthcare
I.V. Systems Division
Attention: Ms. Marcia Marconi
Vice President, Regulatory Affairs
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

APR - 6 1999

Dear Ms. Marconi:

Please refer to your new drug application (NDA) dated March 20, 1998, received April 8, 1998, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Cernevit-12 (multivitamins for infusion).

We acknowledge receipt of your submissions dated June 11 and 16, July 6 and 21, August 6 and 27, October 28, November 10 and 18, and December 18 and 22, 1998, and January 13, February 11 and 19, March 16 (2), and April 1 and 2(fax), 1999.

This new drug application provides for the use of Cernevit-12 (multivitamins for infusion) for (1) a daily multivitamin maintenance dosage for adults and children age 11 years and above receiving parenteral nutrition and (2) for situations where the administration by the intravenous route is required.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted April 2, 1999, and immediate container and carton labels submitted March 16, 1999). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-924." Approval of this submission by FDA is not required before the labeling is used.

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We remind you of your Phase 4 commitments specified in your submissions dated November 18, 1998 (Microbiology) and March 16, 1999 (Chemistry). These commitments, along with any completion dates agreed upon, are listed below.

In your November 18, 1998, submission you commit to the following within 3 months of the approval of the NDA as follows:



In the March 16, 1999, submission you commit to providing the following information to implement the following test changes within 12 months of the approval of the NDA as follows:

