

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

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.

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:

Please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

As of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 6632). We are waiving the pediatric study requirement for this application.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research