NDA: 20,924 Drug: Cernevit-12 IV Multivitamins Date: 4/1/99

To obviate the need to perform 2 phase 4 clinical trials, the following labeling changes were proposed in our t-con with Baxter today:

Indications and Usage section:

Last paragraph:: replace the second sentence with:

DRAFT LABELING

[redacted]

Drug Interactions section:

First paragraph:

Delete the fourth sentence which begins with: "Consult appropriate references..."

DRAFT LABELING

[redacted]

Second paragraph:

Reference the second sentence to the Smith et al article[5]

After the second sentence add: DRAFT LABELING

[redacted]

Dosage and Administration section:

After the third sentence in the first paragraph add: DRAFT LABELING

DRAFT LABELING

[redacted]

References:

DRAFT LABELING

[redacted]

/S/ [redacted]

Jean Temeck, M.D.

/S/ [redacted] 4-1-99

David Orloff, M.D.

cc:
NDA 20-924
HFD-510/J Temeck/D Orloff/S Sobel
HFD-510/C McCann

I.V. Systems Division
Regulatory Affairs

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

Baxter

April 2, 1999

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation II
Division of Metabolic and Endocrine
Drug Products
Central Document Room 14B-19
5600 Fishers Lane - HFD-510
Rockville, MD 20857-1706

Re: NDA 20-924: Cernevit™-12 IV Multivitamins

Response to April 1, 1999 Labeling Comments

-- MINOR AMENDMENT --

Dear Sir or Madam:

Baxter Healthcare Corporation is submitting a revised package insert for the above-referenced product. The modified package insert reflects the revisions proposed by the Agency in its April 1, 1999 letter and agreed upon by Baxter and Agency representatives in a telephone meeting on April 1, 1999.

An electronic version of the revised package insert is provided on the diskette in **Attachment 1**. **Attachment 1** also contains a paper copy of the contents of the diskette. The revised package insert was saved as a Word 97 document and is entitled "dir_ins5.doc". A marked-up, paper copy of the revised insert is provided in **Attachment 2**.

Thank you for incorporating this information into the file. If you have questions or comments, please contact Ms. Linda Coleman or Tamima Itani, Ph.D. at (847) 270-2577.

Sincerely,

Marcia Marconi (LC)

Marcia Marconi
Vice President, Regulatory Affairs
(847) 270-4637
(847) 270-4668 (FAX)

LABEL REVIEW

Application Number: 20-924

Name of Drug: Cernevit™ -12 IV Multivitamins

Sponsor: Baxter Healthcare

Material Reviewed: March 16, 1999

Receipt Date: March 19, 1999

BACKGROUND:

The March 16, 1999, draft labeling was submitted in response to the Agency's labeling recommendations FAXED to the Sponsor on March 8, 1999, as revisions to the February 11, 1999, draft labeling for Cernevit™-12 IV Multivitamins. The labeling recommendations were as follows:

1. **PACKAGE INSERT**

   In the product name which reads *"CERNEVIT™ -12 IV MULTIVITAMINS Lyophilized Sterile Powder for Reconstitution"*, should be revised to read

   DRAFT LABELING

2. **VIAL LABEL**

   a. In the product name which reads *"CERNEVIT™ -12 IV MULTIVITAMINS Lyophilized Sterile Powder for Reconstitution"*, should be revised to read

   DRAFT LABELING

   b. Delete the line after *CERNEVIT™ -12 IV MULTIVITAMINS*

   DRAFT LABELING

APPEARS THIS WAY ON ORIGINAL

2 pages REDACTED
DRAFT LABELING