

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020924

ADMINISTRATIVE/CORRESPONDENCE DOCUMENTS

LABEL REVIEW

Application Number: 20-924

Name of Drug: Cernevit™ -12 (multivitamins for infusion)

Sponsor: Baxter Healthcare

Material Reviewed: April 2, 1999 (Package Insert)

Receipt Date: April 2, 1999 (fax)

BACKGROUND:

The April 2, 1999, draft labeling was submitted in response to the Agency's labeling recommendations FAXED to the Sponsor on April 1, 1999, as revisions to the March 16, 1999, draft labeling for Cernevit™-12 IV Multivitamins.

REVIEW:

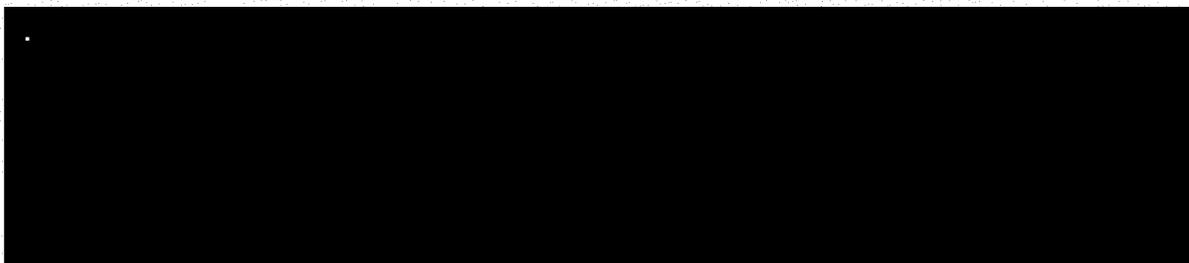
PACKAGE INSERT

The draft labeling for the package insert submitted April 2, 1999, was compared with the draft labeling dated March 16, 1999. The following changes were noted:

Under **INDICATIONS AND USAGE**, paragraph 7, line three which reads,

"No vitamin deficiencies were clinically evident, but blood levels of Vitamins A, C, D, and folic acid declined in a number of subjects who received this formulation as the only vitamin source for 4 to 6 months."

has been revised to read,



Under **DRUG INTERACTIONS**, paragraph 1, line 2, the sentence which reads,

"Consult appropriate references for listing of specific drug vitamin interactions."

has been deleted.

Under **DRUG INTERACTIONS**, paragraph 1, after the last sentence which ends with [REDACTED] the following sentences were added:

[REDACTED]
., DRAFT LABELING
[REDACTED]

Under **DRUG INTERACTIONS**, paragraph 2, after the second sentence which ends “and ascorbic acid,” the following sentence was added:

[REDACTED]
., DRAFT LABELING
[REDACTED]

Under **DRUG INTERACTIONS**, paragraph 2, line three, after the second sentence, which ends “. . . Vitamin C and thiamine,” add footnote [REDACTED] which references the [REDACTED]
[REDACTED]

Under **DOSAGE AND ADMINISTRATION**, paragraph one, line 4, after the sentence which reads, “*After reconstitution, CernevitTM-12 (multivitamins for infusion) should be used immediately or stored under refrigeration for no more than 24 hours.*”, the following sentence was added:

[REDACTED]
., DRAFT LABELING
[REDACTED]

To the **References** section, the following references were added:

[REDACTED]
DRAFT LABELING
[REDACTED]

BOX AND VIAL LABELING:

The box and vial labeling dated March 16, 1999, has been previously submitted to the Agency on March 19, 1999 and was found to be approvable in a previous label review (see label review dated March 22, 1999).

RECOMMENDATION:

The draft labeling for Cernevit™ -12 dated April 2, 1999, included all the requested revisions to the package insert (see April 1, 1999, faxed comments from FDA). The draft labeling dated April 2, 1999 (package insert) and March 16, 1999 (box and vial labeling), with the concurrence of the reviewing staff is approvable.

/S/ [Redacted]

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cc:

- NDA 20-924
- HFD-510/Div. Files
- HFD-510/SMcCort
- HFD-510/Solomon Sobel, M.D.

APPEARS THIS WAY ON ORIGINAL

LABEL REVIEW