

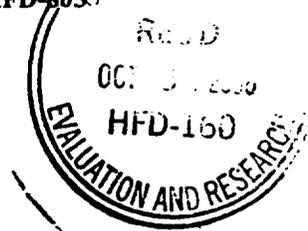
**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-265

MICROBIOLOGY REVIEW

Review for Division of Metabolic and Endocrine Drug Products, HFD-510
Office of New Drug Chemistry, Microbiology Staff, HFD-805
Microbiologists's Review No. 1

October 18, 2000



MICROBIOLOGY REVIEWER: Carol K. Vincent

A. 1. NDA No.: 21-265

DRUG PRODUCT NAME: Multi-12®/K, Pediatric [Multiple Vitamins for Infusion]

APPLICANT and DRUG PRODUCT MANUFACTURER:

Sabex, Inc.
145 Jules-Leger
Boucherville, QC, Canada
J4B 7K8

2. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

Sterile liquid in two vials to be added to not less than 100 mL diluent for parenteral nutrition by infusion; both vials are used for the single dose. Suitable diluents include intravenous dextrose, saline, or similar infusion solutions.

3. METHOD(s) OF STERILIZATION: _____

4. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPAL INDICATION:

Indicated as a daily multivitamin maintenance supplement for infants and children to age 11 receiving parenteral nutrition.

5. DRUG PRIORITY CLASSIFICATION: 5 Standard

B. 1. DOCUMENT DATE: April 20, 2000
2. DOCUMENT RECEIVED FOR REVIEW: May 8, 2000
3. AMENDMENT: October 6, 2000
4. AMENDMENT RECEIVED FOR REVIEW: October 16, 2000
5. COMIS USER FEE DUE DATE: November 17, 2000

6. RELATED NDA: 21-163, Multi-12 / [Multiple Vitamins for Infusion].

C. REMARKS: "Multi-12 /K1 Pediatric [Multiple Vitamins for Infusion] contains vitamin K. This is a "sister" NDA to Multi-12 [Multiple Vitamins for Infusion], NDA 21-163, the adult formulation lacking Vitamin K.

D. CONCLUSION and RECOMMENDATION: We recommend approval of NDA 21-265 from the microbiology prospective for the sterilization process validation for this drug product. See "E. REVIEW NOTES:", below.

CC:
Orig. NDA 21-265
HFD-160/Consult/CKVincent [HFD-805]
HFD-180/Wu/LewisD/McCort
Drafted by: CKVincent/04-20-2000
Revised by: CKVincent/07-26-2000/10-18-2000

Why did you redact this? Andrea says can stay in Per Debbi

IS/
10-18-2000
Carol K. Vincent
Review Microbiologist [HFD-805]
IS/ 10/24/00

(b4)

9 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.