CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-163

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

May 10, 2000

MICROBIOLOGY REVIEWER: Carol K. Vincent

A. 1. NDA No.: 21-163

DRUG PRODUCT NAME: Multi-12® [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 5 mL vials to be added to not less than 500 mL diluent for parenteral nutrition by infusion. 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 suppplement for adults and children aged 11 and older receiving parenteral nutrition.

5. DRUG PRIORITY CLASSIFICATION: Standard

B. 1. DOCUMENT DATE: July 19, 1999

2. DOCUMENT RECEIVED FOR REVIEW: August 3, 1999

3. COMIS USER FEE DUE DATE: July 20, 2000

4. RELATED NDA: 21-265, Multi-12 / K_1 Pediatric [Multiple Vitamins for Infusion]

C. REMARKS: "Multi-12" does not contain vitamin K which may have to be administered separately.

D. CONCLUSION and RECOMMENDATION:

We recommend **approval** of NDA 21-163 from the microbiology prospective for the sterilization process validation information for this drug product. See "E. REVIEW NOTES:", below.

CC:
Orig. NDA 21-163
HFD-160/Consult/CKVincent [HFD-805]
HFD-180/Wu/LewisD/McCort
Drafted by: CKVincent/04-20-2000
Revised by: CKVincent/05-04-2000
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Carol K. Vincent
Review Microbiologist [HFD-805]

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