CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-163

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

NDA 21-163

Food and Drug Administration
Rockville MD 20857

Sabex Inc.
Attention: Ken Muhvich, Ph.D.
Authorized U.S. Agent for Sabex
1818 Circle Road
Ruxton, Maryland USA 21204

MAY 18 2000

Dear Dr. Muhvich:

Please refer to your new drug application (NDA) dated July 19, 1999, received July 20, 1999, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Multi-12® (Multiple Vitamins for Infusion). We acknowledge receipt of your submissions dated December 6, 1999, and January 12 and 28, April 11, and May 9, 10, and 16, 2000.

This new drug application provides for the use of Multi-12® (Multiple Vitamins for Infusion) as a daily multivitamin maintenance supplement for adults and children aged eleven years and older receiving parenteral nutrition or in other situations in which administration by 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.

We remind you of the need to comply with the April 20, 2000, Federal Register notice, *"Parenteral Multivitamin Products: Drugs for Human Use; Drug Efficacy Study Implementation Amendment"*, by June 19, 2000.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and immediate container and carton labels submitted May 16, 2000). 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 21-163." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, 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* 66632). We note that Multi-12® (Multiple

Vitamins for Infusion) is indicated for children aged eleven years and older and is formulated in accordance with the September 17, 1984, Federal Register notice, *"Drugs for Human Use; Parenteral Multivitamin Products; Revocation of Exemption ("Paragraph XIV/Category 11"); Announcement of Effective Formulations; Followup Notice and Opportunity for Hearing."* A separate Federal Register notice, dated January 26, 2000, *"Pediatric Parenteral Multivitamins Products; Drug Efficacy Study Implementation; Announcement of Marketing Conditions,"* specifies a different formulation for use in children younger than eleven years. Parenteral multivitamin drug products formulated as described in the Federal Register notices do not require pediatric studies. Therefore, we waive 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 Sabex's continued cooperation to resolve any problems that may be identified.

In addition, you should 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. 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, call Steve McCort, Consumer Safety Officer, at (301) 827-6415.

Sincerely,

/S/

John K. Jenkins, M.D.
Acting Director
Division of Metabolic and
Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:

Susan Levesque
Vice President, Quality Assurance and Regulatory Affairs
145 Jules-Leger Street
Boucheville, QC, Canada J4B 7K8

cc:
Archival NDA 21-163
HFD-510/Div. Files
HFD-510/S.McCort
HFD-510/DOrloff/JTemeck/RSteigerwalt
HFD-102/JJenkins
HFD-805/PCooney/CVincent
HFD-820/DWu/DLewis
HFD-870/RShore/HAhn
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-102/ADRA (with labeling)
HFD-102/Post-Marketing PM
HFD-104/Peds/V.Kao (with labeling)
HFD-104/Peds/T.Crescenzi (with labeling)
HFD-40/DDMAC (with labeling)
HFI-20/Press Office (with labeling)
HFD-400/OPDRA (with labeling)
HFD-613/OGD (with labeling)
HFD-095/DDMS-IMT (with labeling)
HFD-820/DNDC Division Director
DISTRICT OFFICE

Concurrence: D Lewis 5-7-00/D Wu 5-9-00/R Steigerwalt 5-9-00/R Shore 5-10-00/H Ahn 5-10-00/ C Vincent 5-10-00/P Cooney 5-11-00/ J Temeck 5-11-00/E Galliers 5-7-00, 5-16-00

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APPROVAL (AP)