CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-559

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-559

Sabex 2002 Inc.
Attention: George Zorich
Agent for Sabex 2002 Inc.
c/o Roundtable Healthcare Partners
272 East Deerpath, Suite 350
Lake Forest, IL 60045

Dear Mr. Zorich:

Please refer to your new drug application (NDA) dated August 14, 2002, received August 16, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Infuvite Adult (multiple vitamins for infusion) Pharmacy Bulk Package.

We acknowledge receipt of your submissions dated October 29 and November 15, 2002, and March 10, April 29(2), and May 16 and 21, 2003.

This new drug application provides for a Pharmacy Bulk Package, which is a new presentation, of INFUVITE Adult (multiple vitamins for infusion). INFUVITE Adult Pharmacy Bulk Package is approved for use as a daily multivitamin maintenance supplement for adults and children aged 11 and older receiving parenteral nutrition.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted May 21, 2003, immediate container (Vial 1 and Vial 2) labels, and carton label submitted May 21, 2003) (copies enclosed) 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 an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-559.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Enid Galliers, Chief, Project Management Staff, at (301) 827-6429.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine
Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
package insert, Vial 1 and Vial 2 labels, carton label