CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-646

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-646

Sabex 2002 Inc.
Attention: George Zorich
Agent for Sabex 2002 Inc.
c/o Roundtable Healthcare Partners
272 East Deerpath, Suite 350
Lake Forest, IL 21-64660045

Dear Mr. Zorich:

Please refer to your new drug application (NDA) dated March 31, 2003, received April 1, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Infuvite *Pediatric* Pharmacy Bulk Package (multiple vitamins for infusion).

We acknowledge receipt of your submissions dated May 13, June 6, July 16, October 29, November 26, December 11 and 15, 2003, and January 12, 19, and 23, 2004.

This new drug application provides for a Pharmacy Bulk Package, which is a new presentation of Infuvite *Pediatric* (multiple vitamins for infusion).

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, vial label and carton label submitted January 12, 2004). 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-646**." Approval of this submission by FDA is not required before the labeling is used.

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. We note that you have fulfilled the pediatric study requirement for this application.

If you have any questions, call Holly Wieland, Regulatory Project Manager, at (301) 827-6410.

Sincerely,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Orloff
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