DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-163/S-005

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 supplemental new drug application dated August 15, 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).

We acknowledge receipt of your submissions dated February 4 and 10, 2003.

This supplemental new drug application provides for the addition of a revised stability protocol containing a test for aluminum and the addition of aluminum content information to the vial labels as required by 21 CFR 201.323. The vial labels add the statement "Contains no more than 475 mcg/L of aluminum (combined Vials 1 and 2)." There is also some re-formatting of the package insert, vial, and carton labels.

We completed our review of this application, as amended. This application 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 1 and Vial 2 labels (for the single dose carton and the 5X single dose carton), and carton labels (single dose and 5X single dose) submitted February 4, 2003.

Please submit the FPL electronically 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, 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 supplement NDA 21-163/S-005." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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
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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