DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-163/S-011

Roundtable Healthcare Partners
Attention: George S. Zorich
Authorized Agent for Sabex 2002, Inc.
272 E. Deerpath Street, Suite 350
Lake Forest, IL 60045

Dear Mr. Zorich:

Please refer to your supplemental new drug application dated March 16, 2004, received March 19, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Infuvite *Adult* (multiple vitamins for infusion).

We also refer to your submission dated July 8, 2004.

This supplemental new drug application provides for the addition of the aluminum content statement "Contains no more than 475 µcg/L of aluminum (vials 1 and 2 combined)" to the DESCRIPTION section of the package insert, although its presence is not required per 21 CFR 201.323. This supplement also provides for the addition of "and/or hydrochloric acid" to the pH adjustment section of the single dose and 5X dose carton labels. This is an editorial addition of information already approved in the package insert in Supplement 005.

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 enclosed final printed labeling (FPL) submitted on July 8, 2004, for the package insert and the 5X carton label and in the agreed-upon labeling text for the single dose carton label.

The FPL must be identical to the single dose carton label submitted on March 16, 2004.

Please submit 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 21-163/S-011." Approval of these submissions by the FDA is not required before the labeling is used.

In addition, you must submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5). Current guidance for industry specifies that the content of labeling should be provided in PDF or SPL file format. This new submission requirement was published on December 11, 2003 (68 FR 69009) and was effective June 8, 2004. For additional information, consult the following guidance for industry: *Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004).

Submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
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 Holly Wieland, Regulatory Project Manager, at (301) 827-6410.

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
5X Carton Label

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

/s/

Mary Parks
9/17/04 11:46:04 AM
for Dr. Orloff