



NDA 21-559/S-005

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

Dear Mr. Zorich:

Please refer to your supplemental new drug application dated January 27, 2004, received January 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INFUVITE *Adult* Pharmacy Bulk Package (multiple vitamins for infusion).

We acknowledge receipt of your submission dated January 27, 2004. This submission was accepted for filing as "Supplement- Changes Being Effected 30 (CBE-30)". Upon further review, this submission does not qualify for a CBE-30 because it lacks final printed labeling (FPL). Therefore, we reviewed this submission as a prior approval supplement.

This supplemental new drug application provides an aluminum content statement for the immediate container labels for vials 1 and 2. The aluminum content statement now reads, "Contains no more than 125 mcg/L of aluminum per single dose".

We completed our review of this application. 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 agreed-upon labeling text (immediate container labels [vials 1 and 2] submitted January 27, 2004).

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

Enclosure:

**This is a representation of an electronic record that was signed electronically and
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/s/

David Orloff

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