DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-265/S-015

Sandoz Canada Inc.
Attention: Allison Sherwood, U.S. Agent
Manager, Regulatory Affairs, Sandoz Inc.
2555 W. Midway Blvd.
P.O. Box 446
Broomfield, Colorado 80038-0446

SUPPLEMENT APPROVAL

Dear Ms. Sherwood:

Please refer to your supplemental new drug application dated November 1, 2007, received November 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Infuvite Pediatric (Multiple Vitamins for Infusion).

This "Changes Being Effected" supplemental new drug application provides for changes in the method and validation for the aluminum content test. This revised specification states the product "contains no more than 30 mcg/L of aluminum (combined Vials 1 and Vial 2)". This revision is reflected in changes in the package insert *(Description section)*, carton and container labels.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format for the package insert (PI) submitted November 1, 2007, and the final printed labeling (FPL) for the 5X carton and container (Vial 1 and Vial 2) labels submitted November 1, 2007.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an approved new drug.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

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:

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

REPORTING REQUIREMENTS

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 Haley Seymour, Regulatory Project Manager, at (301) 796-2443.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation

Enclosures:
Package Insert
Vial 1 container label
Vial 2 container label
5 x single dose, 10-vial carton

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

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