



NDA 21-559/S-009

Sandoz Canada Inc.  
Attention: Alison 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 2, 2007, received November 5, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Infuvite Adult Pharmacy Bulk Package (PBP) (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. The revised specification states the product "contains no more than 70 mcg/L of aluminum (combined Vials 1 and 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 2, 2007, and the final printed labeling (FPL) bulk package carton and container (Vial 1 and Vial 2) labels submitted November 2, 2007.

**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](http://www.fda.gov/cder/ddmac).

**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  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

**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

Carton

Vial 1 container label

Vial 2 container label

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/s/

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Mary Parks  
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