



NDA 8-809/S-052

aaPharma
Attention: Christy M. Clark
Regulatory Affairs Analyst
2320 Scientific Park Drive
Wilmington, NC 28405

Dear Ms. Clark:

Please refer to your supplemental new drug application dated December 18, 2003, received December 22, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for M.V.I – 12® (Multi-Vitamin Infusion without vitamin K), unit vial, dual vial, and pharmacy bulk package (PBP).

We acknowledge receipt of your submissions dated April 12, 20, and 21, 2004.

This supplemental new drug application provides for the reformulation of the drug product to include revised formula amounts of Vitamin C, Vitamin B₆, Vitamin B₁, and folic acid. Also, the established name has been changed from “multi-vitamin infusion” to “multi-vitamin infusion without vitamin K.”

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 inserts (unit vial, dual vial, and PBP) submitted April 21, 2004 (enclosed)
Carton labels (unit vial, dual vial, and PBP) submitted December 18, 2004
Container labels, (unit vial, vial 1, vial 2, PBP vial 1 and PBP vial 2) submitted
December 18, 2004.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated “FPL for approved supplement NDA 8-809/S-052” Approval of this submission by FDA is not required before the labeling is used.

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 two copies of both the promotional materials and the package inserts 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, please call Holly Wieland, Regulatory Project Manager, at (301) 827-6410.

Sincerely,

{See appended electronic signature page}

David Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:

Package Insert- Unit Vial

Package Insert- Dual Vial single dose, and PBP

**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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