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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 8-809/S-054 **PRIOR APPROVAL SUPPLEMENT**

Mayne Pharma (USA) Inc.
Attention: Steve Richardson
Director, Regulatory and Medical Affairs
Mack-Cali Centre II
650 From Road, Second Floor
Paramus, New Jersey 07652

Dear Mr. Richardson:

We have received your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: M.V.I.-12 (multi-vitamin infusion without vitamin K)

NDA Number: 8-809

Supplement number: 054

Date of supplement: August 20, 2004

Date of receipt: August 23, 2004

We also refer to your submission dated August 31, 2004.

This supplemental new drug application provides for a reformulation of M.V.I.-12 to include different amounts of vitamins C, B_6, B_1, and folic acid, a change in the established name to "multi-vitamin infusion without vitamin K", and a change in the "INDICATIONS AND USAGE" section of the package insert. The revised indication is as follows:

> "This formulation is indicated for the prevention of vitamin deficiency and thromboembolic complications in people receiving home parenteral nutrition who also receive warfarin-type anticoagulant therapy."

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 enclosed labeling:

- package insert for the two-chambered, single-dose vial, product ID number: XXXXXX, revision date: 08/2004, submitted August 20, 2004

- package insert for the single-dose, dual vial set and the Pharmacy Bulk Package (PBP), product ID number: 808604-00 revision date: 08/2004 submitted August 20, 2004

  However, the ZIPcode for Mayne Pharma should be changed to "07652".

The final printed labeling (FPL) must also be identical to the submitted labeling except for appropriate changes to the manufacturer identification:

- carton labels (unit vial, dual vial, and PBP) submitted December 18, 2003

- container labels (unit vial, vial 1, vial 2, PBP vial 1 and PBP vial 2) submitted December 18, 2003

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).

For administrative purposes, this submission should be designated "FPL for approved supplement NDA 8-809/S-054." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional material that you propose to use for this product. Submit all proposed material 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, call Holly Wieland, Regulatory Project Manager, at (301)827-6410.

Sincerely,

{See appended electronic signature page}

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

Enclosures:
Package Insert for the two-chambered, single-dose vial
Package Insert for the single-dose, dual-vial set and the Pharmacy Bulk Package

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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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