



NDA 18-920/S-024

NeoSan Pharmaceuticals  
Attention: Dr. Phillip S. Tabbiner  
President  
2320 Scientific Drive  
Wilmington, NC 28405

Dear Dr. Tabbiner:

Please refer to your supplemental new drug application dated December 22, 2000, received December 26, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for M.V.I. *Pediatric* (Multi-Vitamins for Infusion).

We acknowledge receipt of your submissions dated January 24 and March 12, 2001. The March 12, 2001, submission contained final printed labeling.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert and container labeling in response to the January 26, 2000, Federal Register Notice "*Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition*" and the January 26, 2001, Federal Register Notice "*Aluminum Used in Total Parenteral Nutrition; Delay of Effective Date.*"

## 1. PACKAGE INSERT

A **WARNINGS** section containing the following information has been added.

*WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.*

*Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 µg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.*

**2. IMMEDIATE CONTAINER LABEL**

The following has been added:

*“When reconstituted in accordance with the package insert instructions, the concentration of aluminum will be no more than 42 µg/L.”*

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling for the package insert submitted on March 12, 2001 (enclosed) and the vial label submitted on March 12, 2001. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE

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

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David Orloff

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