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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Date

4-13-05

Public Hearing

4-14-05

Certifier

*[Signature]*

[Docket No. 1979N-0113 (formerly Docket No. 79N-0113); DESI 2847]

**Drugs for Human Use; Drug Efficacy Study Implementation; Parenteral Multivitamin Drug Products; Announcement of Unlawful Formulations**

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is declaring unlawful the unapproved marketing of certain parenteral multivitamin drug products for which a hearing was requested, but for which the sponsors have withdrawn the hearing requests. FDA is taking this action because the products lack substantial evidence of effectiveness as fixed combination drug products.

**DATES:** This notice is effective [*insert date 30 days after date of publication in the Federal Register*].

**ADDRESSES:** Requests for an opinion of the applicability of this notice to a specific product should be identified with Docket No. 1979N-0113 and reference number DESI 2847 and directed to the Division of New Drugs and Labeling Compliance (HFD-310), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Mary Catchings, Center for Drug Research and Evaluation (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of September 17, 1984 (49 FR 36446) (the September 1984 notice), FDA

announced the conditions for marketing an effective parenteral multivitamin drug product. The effective 12-vitamin formulation set forth in the notice was based on the clinical evaluation of a guideline formulation recommended by the American Medical Association. (In the **Federal Register** of April 20, 2000 (65 FR 21200), FDA amended the September 1984 notice by increasing the dosage of certain vitamins and by adding vitamin K to the formulation.) The September 1984 notice, published as part of the Drug Efficacy Study Implementation, also revoked the temporary exemption (paragraph XIV, category XI) for three original formulation products that had been allowed to remain on the market while guideline formulations were studied. The notice stated that FDA was unaware of any adequate and well-controlled clinical trials meeting the requirements of section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)), 21 CFR 300.50, and 21 CFR 314.111(a)(5) (now 21 CFR 314.125(b)(5)) and demonstrating the effectiveness of these products; therefore, FDA proposed to withdraw approval of the portions of the new drug applications (NDAs) pertaining to the original formulations. The notice offered affected parties an opportunity for a hearing on the proposal.

In response to the September 1984 notice, Hoffmann-LaRoche, Inc., USV Pharmaceutical Corp., LyphoMed, Inc. (subsequently acquired by American Pharmaceutical Partners, Inc.), and Carter-Glogau Laboratories, Inc. (subsequently acquired by Schein Pharmaceutical, Inc.), submitted hearing requests. Hoffmann-LaRoche and USV voluntarily withdrew their hearing requests shortly after they were submitted; therefore, FDA withdrew approval of the NDAs for the Hoffmann-LaRoche and USV products in **Federal Register**

notices of February 28, 1985 (50 FR 8193), and December 27, 1985 (50 FR 53014). The following hearing requests were still pending:

1. MultiVitamin Concentrate; No NDA; American Pharmaceutical Partners, Inc. (APP), 2045 North Cornell Ave., Melrose Park, IL 60160-1002. Each 5-milliliter vial of MultiVitamin Concentrate contained ascorbic acid (vitamin C) 500 milligrams (mg), vitamin A (retinol) 3 mg (10,000 International Units (I.U.)), vitamin D (ergocalciferol) 25 micrograms (1,000 I.U.), thiamine (B1) 50 mg, riboflavin (B2) 10 mg, pyridoxine (B6) 15 mg, niacin (B3) 100 mg, pantothenic acid 25 mg, and vitamin E 3 mg (5 I.U.).

2. The hearing request, which named no specific product, referenced products named in the September 1984 notice; No NDA; Schein Pharmaceutical, Inc. (Schein), 100 Campus Dr., Florham Park, NJ 07932.

In letters dated May 27, 1999, and April 8, 2003, Schein and APP, respectively, withdrew the hearing requests previously submitted regarding parenteral multivitamin products. The letter from APP noted that it had discontinued marketing MultiVitamin Concentrate. Accordingly, there are no pending hearing requests submitted in response to the September 1984 notice of opportunity for hearing. No parenteral multivitamin product remains exempt under the paragraph XIV, category XI exemption.

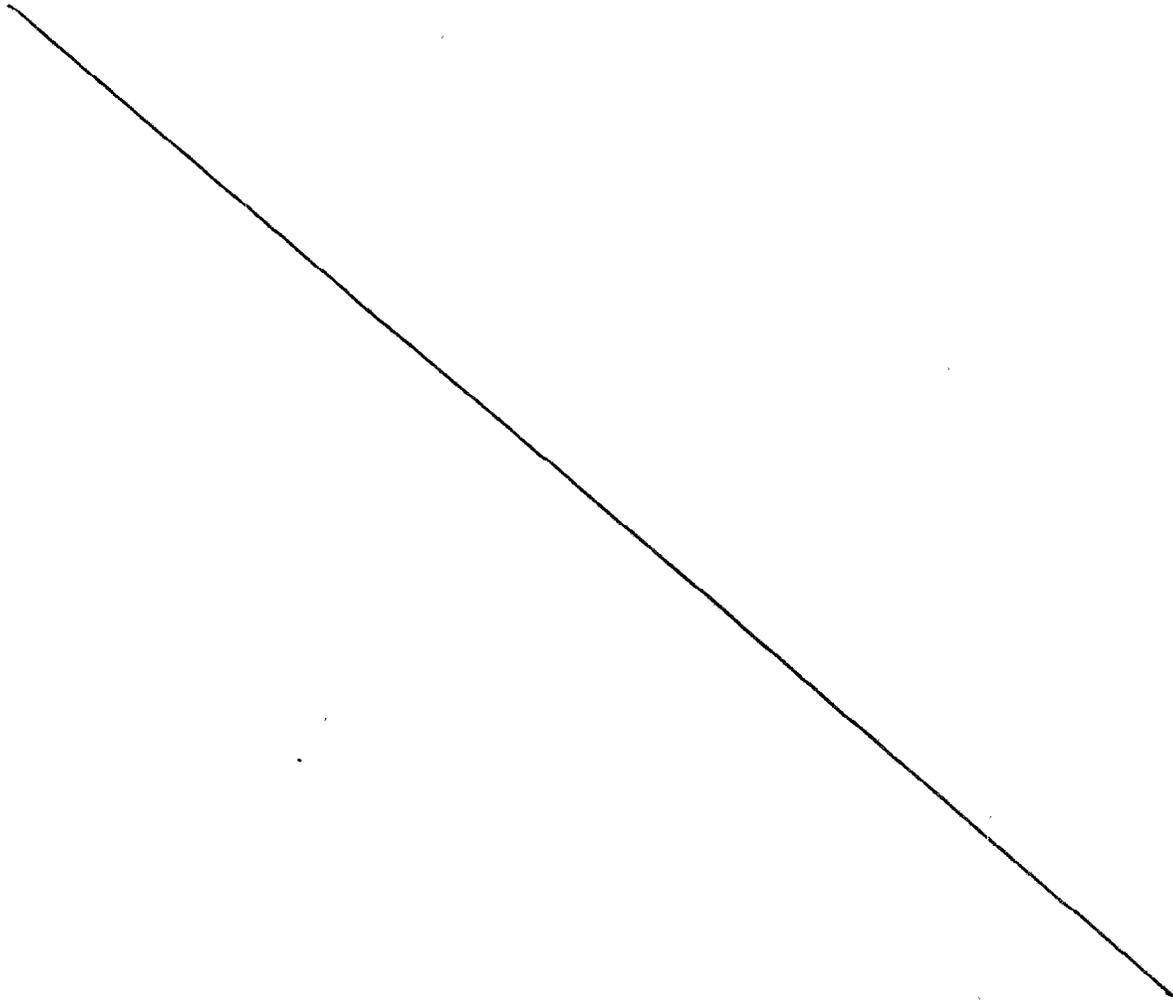
This notice applies to any drug product that is identical, related, or similar to the products specified and referenced previously in this document and is not the subject of an approved NDA (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of New Drugs and Labeling Compliance (see **ADDRESSES**).

Based on the information presented in the September 1984 and April 20, 2000, **Federal Register** notices, the Acting Director of the Center for Drug

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Evaluation and Research, under the act (section 505(e)) and under authority delegated to him (~~21 CFR 5.100~~)<sup>7</sup>, finds that, on the basis of new information on these drugs, evaluated with the evidence available previously, there is a lack of substantial evidence that the products named and referenced previously will have the effects they are purported or represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, based on the foregoing finding, MultiVitamin Concentrate and the original formulation parenteral multivitamin product(s), for which Schein requested a hearing, are declared unlawful, effective [*insert date 30 days after date of publication in the Federal Register*].



Shipment in interstate commerce of these drug products or any identical, related, or similar product that is not the subject of an approved NDA will then be unlawful.

Dated: 4/5/05  
April 5, 2005.



Steven Galson,  
Acting Director,  
Center for Drug Evaluation and Research.



[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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