DATES: This notice is effective May 16, 2005.

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 Evaluation and Research, under the act (section 505(e)) and under authority delegated to him (21 CFR 5.100), 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 May 16, 2005.

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: April 5, 2005.

Steven Galson,

Acting Director, Center for Drug Evaluation and Research.

[FR Doc. 05–7532 Filed 4–13–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Drug Safety and Risk Management Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will held on May 18 and 19, 2005, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Shalini Jain, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: *jains@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512535. Please call the Information Line for up-to-date information on this meeting.

Agenda: This is the first in a series of meetings related to the issues in drug safety and FDA. This 2-day meeting will explore issues related to FDA's risk assessment program for marketed drugs. There are a number of methods that FDA uses in risk assessment of marketed drugs, including review and analysis of spontaneous reports of

adverse events, drug use data, healthcare administrative data, epidemiologic and observational studies, clinical trials, and active surveillance systems. Considerations will include the advantages and disadvantages of the current system for safety signal detection, and proposals for short-term and long-term ways to improve the current system. The background materials for this meeting will be posted 1 business day before the meeting on the FDA Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to the Drug Safety and Risk Management Advisory Committee.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 9, 2005. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on May 18, 2005, and between approximately 11:10 a.m. and 11:40 a.m. on May 19, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 9, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shalini Jain at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 7, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–7458 Filed 4–13–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0122]

Draft Guidance for Industry on Exploratory Investigational New Drugs Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Exploratory IND Studies.'' This draft guidance clarifies what preclinical and clinical issues (including chemistry, manufacturing, and controls issues) should be considered when planning exploratory studies in humans, including studies of closely related drugs or biologics, under an investigational new drug (IND) application. This draft guidance emphasizes the concept that limited investigations in humans can be initiated with more limited preclinical support because such studies present fewer potential risks than do traditional phase 1 studies that look for dose-limiting toxicities.

DATES: Submit written or electronic comments on the draft guidance by July 13, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: David Jacobson-Kram, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5346.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Exploratory IND Studies.'' In its March 2004 Critical Path Report, the agency explained that to reduce the time and resources expended during early drug development on candidates that are unlikely to succeed, tools are needed to allow developers to distinguish earlier in the process those candidates that hold promise from those that do not. This guidance describes some exploratory approaches that will protect human subjects while providing early information about candidate performance in humans.

Exploratory IND studies have a number of different goals. In some cases, an exploratory study can help developers gain an understanding of the relationship between a specific mechanism of action and the treatment of a disease. In other cases, a study can provide important information on pharmacokinetics, including, for example, biodistribution of a candidate drug. Whatever the goal of the study, exploratory IND studies can help sponsors identify, early in the process, promising candidates for continued development.

Existing regulations allow a great deal of flexibility in terms of the amount of data that need to be submitted in an IND application, depending on the goals of an investigation, the specific human testing being proposed, and the expected risks. Nevertheless, sponsors have not always taken advantage of that flexibility and limited, early phase 1 studies, such as those described in this document, are often supported by a more extensive preclinical database than is needed. In many cases, a more extensive workup is done because sponsors intend to move immediately into a more traditional phase 1 trial if the screening results are favorable. Because exploratory studies will typically involve administering either subtherapeutic doses of a product, or doses expected to produce a pharmacological, but not a toxic effect, the potential risk to human subjects is less than for a traditional phase 1 study that, for example, seeks to establish a maximally tolerated dose.

This guidance applies to exploratory studies (i.e., early phase 1 clinical studies), involving investigational new drug and biological products, that assess feasibility for further development of a drug or biological product. For the purposes of this guidance the phrase ''exploratory study'' is intended to describe clinical trials that occur very early in phase 1, involve very limited human exposure, and often have no therapeutic intent.

Typically, these exploratory studies are conducted prior to the traditional