Place: Agency for Healthcare Research & Quality, 540 Gaither Road, Conference Center, Rockville, Maryland 20850.

Contact Person: Anyone wishing to obtain information regarding this meeting should contact Thomas Boyce, Office of Performance Accountability, Resources and Technology, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850, (301) 427–1796.

Dated: April 4, 2005.

Carolyn M. Clancy,

Director.

[FR Doc. 05–7474 Filed 4–13–05; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Compassion Capital Fund Evaluation.

OMB No.: New Collection.

Description: This proposed information collection activity is for two rounds of surveys to be completed by faith-based and community organizations participating in the Compassion Capital Fund (CCF) evaluation project. The first survey will be conducted as a baseline survey and the second will be a follow-up survey conducted several months later.

The CCF evaluation is an important opportunity to examine the effectiveness of the Compassion Capital Fund in meeting its objective of improving the capacity of faith-based and community organizations. The evaluation will involve up to 1,000 faith-based and community organizations that seek services from CCF-funded intermediary organizations. Information will be collected from these faith-based and community-based organizations to assess change and improvement in various areas of capacity. The study design includes the random assignment of faith-based and community organizations to either a treatment group that receives capacity-building services from a CCF intermediary grantee or to a control group that does not. The impact of the services provided by intermediaries, primarily through sub-awards and/or technical assistance (TA), will be determined by comparing the changes in organizational and service capacity of the recipient organizations with those of the control group.

Respondents: The respondents for both the baseline and follow-up data collection will be faith-based and community organizations that seek sub-awards or TA from selected CCF intermediary grantees. The baseline survey will be primarily self-administered and is expected to be completed as part of the intermediary's sub-award application or TA request process. The follow-up survey also will be primarily self-administered and contain questions similar to those in the baseline survey as well as additional questions related to services received from the intermediary or other organizations. It is expected that the follow-up survey will be administered approximately 9–12 months after random assignment. As needed to increase response rates, the survey will be administered by telephone to organizations that do not initially return a completed survey.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Baseline Survey	1,000		1.33 hours (20 minutes)	330
Follow-up Survey	1,000		1.42 hours (25 minutes)	420
Estimated Total Annual Burden Hours				750

Annual Burden Estimates

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447. Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 11, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–7517 Filed 4–13–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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.

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 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