FDA 356h. Until further notice, if the biological product is not specified in § 601.2(c), applicants should continue to submit an ELA and a PLA application on the CBER forms listed below in this notice.

This collection of information involves the following forms:
Form FDA 2599, ''Establishment License Application for the Manufacture of Blood and Blood Components;''
Form FDA 2599a, ''Supplement to Establishment License Application for the Manufacture of Blood and Blood Components;''
Form FDA 2600, ''Product License Application for the Manufacture of Source Plasma;''
Form FDA 2600b, ''Product License Application for Therapeutic Exchange Plasma;''
Form FDA 3066, ''Product License Application for Manufacture of Blood Grouping Reagents;''
Form FDA 3086, ''Product License Application for the Manufacture of Reagent Red Blood Cells;''
Form FDA 3096, ''Product License Application for the Manufacture of Anti-Human Globulin;''
Form FDA 3098, ''Product License Application for the Manufacture of Whole Blood and Blood Components;''
Form FDA 3098a, ''Product License Application for Red Blood Cells;''
Form FDA 3098b, ''Product License Application for Plasma;''
Form FDA 3098c, ''Product License Application for Platelets;''
Form FDA 3098d, ''Product License Application for Cryoprecipitated Antihemophilic Factor;''
Form FDA 3098e, ''The Manufacture of Products Prepared by Cytapheresis;''
Form FDA 3210, ''Application for Establishment License for Manufacture of Biological Products;''
Form FDA 3213, ''Application for License for the Manufacture of Allergenic Products;''
Form FDA 3214, ''Application for the Manufacture of a Human Plasma Derivative;'' and
Form FDA 3314, ''Product License Application for the Manufacture of Human Immunodeficiency Virus for In-Vitro Diagnostic Use.''

Respondents to this collection of information are manufacturers of biological products. The reporting burden for the current collection of information using CBER's license application forms under OMB control number 0910–0124 was reported to OMB as part of the total burden for the agency's collection of information using Form FDA 356h. This collection of information using Form FDA 356h was assigned OMB control number 0910–0338 and approved by OMB on April 23, 1997. The approval for OMB control number 0910–0338 expires on April 30, 2000. The announcement of OMB's approval was published in the **Federal Register** of May 19, 1997 (62 FR 27262).

Under OMB control number 0910–0338, FDA estimated that CBER's portion of the reporting burden for collection of information using Form FDA 356h was 76,200 hours. The 76,200 hours reflected the future use of Form FDA 356h by all manufacturers of biological products. The number of manufacturers of biological products that are already using Form FDA 356h would account for approximately 3,000 hours of the total burden hours. The other 73,200 hours would account for manufacturers who may not have completed the transition to using Form FDA 356h and still need to use other license application forms. FDA expects that all manufacturers of biological products will begin to use Form FDA 356h during 1998.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Forms	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
601.2 and 601.12	FDA 2599, 2599a, 2600, 2600b, 3066, 3086, 3096, 3098, 3098a, 3098b, 3098c, 3098d, 3098e, 3210, 3213, 3214, and 3314	376	4.9	1,830	40	73,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23838 Filed 9–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92F–0397]

Great Lakes Chemical Corp.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 2B4343) proposing that the food additive regulations be amended to provide for the safe use of an aqueous solution of 1-bromo-3-chloro-5,5-dimethylhydantoin as a sanitizing solution to be used on food processing equipment and utensils and on food-contact surfaces in public eating places.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December 7, 1992 (57 FR 57838), FDA announced that a food additive petition (FAP 2B4343) had been filed by Great Lakes Chemical Corp., P.O. Box 2200, West Lafayette, IN 47906. The petition proposed to amend the food additive regulations in § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) to provide for the safe use of an aqueous solution of 1-bromo-3-chloro-5,5-dimethylhydantoin as a sanitizing solution to be used on food processing equipment and utensils and on food-contact surfaces in public eating places.

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170), which was enacted on August 3, 1996, amended the Federal Food, Drug, and Cosmetic Act (the act) and provided the Environmental Protection Agency (EPA) with the regulatory authority over the petitioned use of this substance. Under FQPA, the petitioned use of this

substance is regulated as a pesticide chemical under section 408 of the act (21 U.S.C. 346a). Thus, post-FQPA, the petitioned use of this substance is no longer subject to FDA's regulatory authority as a food additive under section 409 of the act (21 U.S.C. 348).

In response to a request by the petitioner, which was prompted by the change in regulatory authority over the antimicrobial substance that is the subject of this petition, FDA transferred the records for FAP 2B4343, including all of FDA's reviews of information in the petition, to EPA. Great Lakes Chemical Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: July 15, 1998.

George H. Pauli,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–23837 Filed 9–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pharmacy Compounding 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: Pharmacy Compounding 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 be held on October 14, 15, and 16, 1998, 8:30 a.m. to 5:30 p.m.

Location: Advisory Committee conference room, rm. 1066, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852.

Contact Person: Kimberly L. Topper or John B. Schupp, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857–1000, 301–827–7001, or e-mail Topperk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12440. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will: (1) Address those bulk drug substances that are neither components of FDA approved products nor covered by a United States Pharmacopeia monograph for inclusion on a list of bulk drug substances that may be used in compounding that qualifies for the applicable statutory exemptions, and (2) review drug products to be included on a list that have been withdrawn or removed from the market for reasons of safety or efficacy that may not be used in compounding that qualifies for the applicable statutory exemptions.

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 September 30, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 30, 1998, 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.

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

Dated: July 27, 1998.

Michael A. Friedman.

Deputy Commissioner for Operations.

[FR Doc. 98–23836 Filed 9–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Special Projects of National Significance; Integrated Service Delivery Model

AGENCY: Health Resources and Services Administration.

ACTION: Notice of limited competition for grant funds.

SUMMARY: The Health Services Administration (HRSA) announces that approximately $100,000 is available for grants from the Special Projects of National Significance (SPNS) Program, funded under the authority of Section 2691 of the Public Health Service Act, as established by the Ryan White Care Act Amendments of 1996, Public Law 104–148, dated May 20, 1996.

These awards will be limited to Los Angeles County, California. Applicants may apply for project periods of up to 3 years. The purpose of this limited competition is to support the development and evaluation of models of care that (a) target the African American community in Los Angeles County, (b) can be replicated in other similar localities, and (c) address the formal linkage and integration of HIV ambulatory medical care (including primary medical care) and mental health, substance abuse treatment and/or other critical HIV services.

The SPNS Program is designed to demonstrate and evaluate innovative and potentially replicable HIV service delivery models. The authorizing legislation specifies three SPNS Program objectives: (1) to assess the effectiveness of particular models of care; (2) to support innovative program design; and (3) to promote replication of effective models. The SPNS program will provide technical assistance and support for evaluation studies.

DATES: Applications for these announced grants must be received in the Grants Management Branch by the close of business September 24, 1998 to be considered for competition. Applications will meet the deadline if they are either (1) received on or before the deadline date or (2) postmarked on or before the deadline date, and received in time for submission to the objective review panel. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted as proof of timely mailing. Applications received after the deadline will be returned to the applicant.

ADDRESSES: Grant application kits may be obtained from the HRSA Grants Application Center by calling 1–888–333-HRSA. Additional information regarding business, administrative, and fiscal issues related to the awarding of grants under this Notice may be requested from Mr. Neal Meyerson, Grants Management Branch, HIV/AIDS Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 7–27, Rockville, Maryland 20857. The telephone number is (301) 443–5906 and the FAX number is (301) 594–6096. Applicants for grants will use Form PHS 5161–1, approved under OMB Control No. 0937–0189. Completed applications should be sent to the Grants Management Officer, c/o HRSA Grants Application Center, 40 West Gude Drive, Rockville, Maryland 20850.

FOR FURTHER INFORMATION: Additional technical information may be obtained from the Office of Science and