ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| ACF–118 | 56 | .5 | 162.57 | 4,552 |
| Estimated Total Annual Burden Hours | | | | 4,552 |

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 Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. 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, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 25, 2000.

**Bob Sargis,**

*Reports Clearance Officer.*

[FR Doc. 00–22298 Filed 8–30–00; 8:45 am]

**BILLING CODE 4184–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Blood Products 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). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Blood Products 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 September 14, 2000, 8 a.m. to 5 p.m. and September 15, 2000, 8 a.m. to 4 p.m.

*Location:* Hilton, 620 Perry Pkwy., Gaithersburg, MD.

*Contact Person:* Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On September 14, 2000, the following committee updates are tentatively scheduled: (1) Summary of the Public Health Service Advisory Committee on Blood Safety and Availability meeting, (2) Hepatitis C virus lookback, (3) factor VIII and von Willebrand factor standards, and (4) shortage issues (blood components and recombinant factor VIII). In the morning, the committee will hear presentations, and discuss and make recommendations on the human immunodeficency virus (HIV) p24 antigen testing of plasma for fractionation (potential criteria for discontinuation). In the afternoon, the committee will hear presentations, and discuss and make recommendations on deferral, as blood or plasma donors, of males who have had sex with males. On September 15, 2000, the following updates of recent meetings and workshops are tentatively scheduled regarding: (1) Successful practices of recruiting blood donors, (2) cord blood, (3) tissue meeting on bone products, and (4) the joint meeting of the Transmissible Spongiform Encephalopathies Advisory Committee and the Vaccine and Related Biological Products Advisory Committee meeting. In the morning, the committee will hear presentations, and discuss and make recommendations on the current utility of screening blood donors for syphilis. In the afternoon, the committee will sit as a medical device panel for the classification of human leukocyte antigens (HLA) devices, and will hear the report of the intramural site visit of the Laboratory of Molecular Virology, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review (OBRR).

*Procedure:* On September 14, 2000, from 8 a.m. to 5 p.m. and on September 15, 2000, from 8 a.m. to 3:30 p.m., the meeting is open to the public. 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 1, 2000. Oral presentations from the public will be scheduled from approximately 9:30 a.m. to 11:45 a.m. and 3:30 p.m. to 4 p.m. on September 14, 2000; and from 11 a.m. to 11:30 a.m. and 1:45 p.m. to 2:15 p.m. on September 15, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 28, 2000, and submit arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the September 14 and 15, 2000, Blood Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Blood Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

*Closed Committee Deliberations:* On September 15, 2000, from 3:30 p.m. to 4 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of the review of individual

research programs in the Division of Emerging and Transfusion Transmitted Diseases, OBRR, Center for Biologics Evaluation and Research.

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

Dated: August 24, 2000.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 00–22463 Filed 8–29–00; 2:17 pm]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Predicting Human Dose-Response Relationships From Multiple Biological Models: Issues With Cryptosporidium Parvum; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop sponsored by the interagency Risk Assessment Consortium (RAC) on the topic ''Predicting human dose-response relationships from multiple biological models: Issues with *Cryptosporidium parvum*.'' The purpose of the workshop is to discuss the use of human and nonhuman models of infection and disease to predict human dose-response relationships for foodborne pathogens. The meeting will focus on research programs that are attempting to correlate dose-response data from human and nonhuman models, using the water- and food-borne parasite *C. parvum* as a sample organism. In the morning session, the meeting will also include a presentation, targeted to the public, on the role that dose-response modeling plays in setting food safety policy. The afternoon session will include a panel-led technical discussion of both biological models and mathematical analysis (modeling) of biological data. In addition, an opportunity for public comment will be provided.

*Date and Time:* The meeting will be held on September 28, 2000, from 8:30 a.m. to 5 p.m.

*Location:* The meeting will be held at the Conference Center (rm. 1D00), United States Department of Agriculture (USDA) Center at Riverside, 4700 River Rd., Riverdale MD 20737–1238. Please see transportation information in the **SUPPLEMENTARY INFORMATION** section.

*Contact:* Lauren Posnick for Center for Food Safety and Applied Nutrition (CFSAN) (HFS–308), FDA, 200 C St. SW., Washington, DC 20204, 202–205–4588, lposnick@cfsan.fda.gov, or Wesley Long, CFSAN (HFS–006), FDA, 200 C St. SW., Washington, DC 20204, 202–205–4024.

*Registration:* Preregistration is required by September 25, 2000. Walk-in registration is discouraged. Register online at www.foodriskclearinghouse.umd.edu. or send registration information (name, title, affiliation, address, e-mail address, telephone and fax numbers) to Shiho Sasamoto, CFSAN (HFS–006), 200 C St. SW., Washington, DC 20204, FAX 202–260–1654, 202–205–4355. If possible, please indicate whether you plan to drive and park your car in the Riverside lot. There is no registration fee. If you need special accommodations due to a disability, please contact Wesley Long at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** Risk assessment generally characterizes the nature and magnitude of the risks associated with hazards to human health. A risk assessment provides an opportunity to organize scientific information and thus helps to clarify the necessary assumptions and degree of scientific certainty of the data used in the risk assessment. Risk assessments require specific information on the hazard and on the exposed populations to provide meaningful information to public health officials; this information may be considered in the development of risk-management decisions. Although risk assessment methods are fairly well established for evaluating chemicals in food, risk assessment for foodborne pathogens is far less developed. The May 1997 National Food Safety report to the President noted that an intensive commitment is necessary to fill this gap and develop critically needed methods for analyzing food safety data and addressing its uncertainty.

A component of this effort has been the establishment of a joint RAC composed of Federal agencies with food safety risk-management responsibilities. The role of the consortium is to advance the science of microbial food safety risk assessment; to serve as advisors for direction and review of Risk Assessment Clearinghouse activities; and to assist agencies in fulfilling their specific food safety regulatory mandates. In accordance with these goals, the RAC will host an open public meeting on dose-response relationships for human infections with the food- and waterborne parasite *C. parvum*.

The dose-response relationship for a foodborne pathogen describes the quantitative likelihood of humans becoming infected or ill given exposure to a certain number (or dose) of pathogens. In general, researchers have proposed using both human clinical trials and nonhuman biological models as sources of data for establishing dose-response relationships. Both approaches are problematic: Human trials are complicated by ethical difficulties and both human trials and nonhuman biological models may not accurately represent real world dose-response relationships in humans. This meeting will review research programs that are attempting to estimate human dose-response relationships from human, animal, and in vitro models, focusing on *C. parvum* as a model organism. Speakers at the meeting will discuss the relative usefulness of different types of biological models for *C. parvum*, the potential for integrating data from different types of models, and the use of biological data to develop mathematical models of human dose-response relationships for *C. parvum* infections.

Specifically, the draft agenda includes presentations on the following topics: (1) Risk communication and dose-response modeling, including the importance of dose-response modeling to the scientist and the public, and the need for comprehensible dose-response models that can form the basis for public policy formulation; (2) parasite and host factors that affect the *Cryptosporidium*-human dose-response relationship, such as strain virulence, susceptible populations, and infection dynamics; (3) biological models of *Cryptosporidium* infection, including cell culture, animal, and human models; (4) the development and utility of mathematical models based on data from various biological models; and (5) a scientific panel discussion on such issues as: (a) The usefulness of biological models as a source of data for modeling human dose-response relationships, (b) the potential for integrating data from different biological models, (c) the adequacy of current models for modeling human dose-response relationships, and (d) the need to identify alternate models or data.

The meeting will also include a public comment period for general comments on *Cryptosporidium*, dose-response modeling, or other activities or issues related to risk assessment. For planning purposes, people who wish to speak during the public comment period must register in advance by contacting Wesley Long or Lauren Posnick (see *Contact* information above).

Parking at the USDA–Riverside Center is limited. Entry into the parking lot costs $2 (exact change required). The