register to attend or present at the workshop. You must register by close of business on April 15, 2006, to attend or participate.

We are opening a docket to receive your written or electronic comments (see **ADDRESSES**). Written or electronic comments must be submitted to the docket by June 15, 2006.

ADDRESSES: The public workshop will be held at the Centers for Disease Control and Prevention, 1600 Clifton Rd., NE., CDC Roybal Campus, Bldg. 19, Auditorium A, Atlanta, GA 30333.

Submit written comments to 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*.

FOR FURTHER INFORMATION CONTACT: Workshop Coordinator, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779, FAX: 301–827–4312, e-mail: *cderexsec@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding a Public Workshop?

This workshop has been developed in response to reports of morbidity and mortality associated with *C. sordellii* and *C. difficile*. These reports include cases and clusters of *C. sordellii* toxic shock syndrome following treatment with mifepristone, *C. sordellii* sepsis associated with tissue grafts, and rapidly fatal toxin-mediated cases of community-associated *C. difficile* infection. The primary goal of the workshop is to bring together scientific and public health experts to develop a draft research agenda. This research agenda is expected to lead to better understanding of the virulence, pathogenesis, host factors, and nonantimicrobial risk factors contributing to these reports and to identify research needs and priorities in these areas. As part of a research agenda, the workshop will assist in the development of recommendations for detecting cases and conducting surveillance. The meeting focus will be on increasing our understanding of severe community associated *C. difficile* and *C. sordellii* disease and of disease in otherwise healthy populations previously thought to be at low risk.

II. What Are the Issues We Intend to Address at the Workshop?

1. What clinical and laboratory surveillance data are needed to help guide infection prevention?

2. Are there characteristics of the clinical presentations of these infections that suggest measures that could prevent or mitigate them?

3. How does our current understanding of the pathophysiology and risk factors associated with these infections inform future research and public health actions?

4. What are the gaps in basic research that are critical to a better understanding of the pathogenesis of *C. sordellii* and *C. difficile?*

III. How Do You Register?

Registration is required to attend or participate in the workshop. Your registration must be received by the close of business on April 15, 2006. Registration is free. Seats are limited, so please register as soon as possible. Space will be filled in order of receipt of registration. Those registered will receive confirmation on April 18, 2006. Registration will close after available space fills. You will not be notified if registration has closed before your registration is received. There will be no on-site registration the day of the workshop.

Time will be allowed during the scheduled agenda for attendees to ask questions of panelists, to participate in the discussion, and to provide input to the sponsoring agencies on future research, surveillance, and case detection. In addition, we strongly encourage written submissions to the docket.

If you need special accommodations due to disability, please contact the Workshop Coordinator (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the workshop.

Registration Form Instructions: To register to attend the workshop, complete the following registration form and submit via:

- E-mail: *cderexsec@cder.fda.gov*;
- FAX: 301–827–4312; or
- Mail to: Food and Drug Administration, Center for Drug Evaluation and Research, Office of Executive Programs, Executive Operations Staff (HFD–006), 5600 Fishers Lane, Rockville, MD 20857, Attn: Workshop Coordinator.

Name: _____
Company Name: _____
Mailing Address: _____
City: _____ State: _____
Zip Code: _____
Phone: ( ) _____
Fax: ( ) _____
E-mail: ( ) _____
U.S. Citizen Yes/No (Required by CDC Security)

IV. How Should You Send Comments on the Issues?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. To ensure consideration of your comments, we must receive any written or electronic comments by the date indicated (see **DATES**).

V. Will Meeting Transcripts Be Available?

You can examine a transcript of the May 11, 2006, public workshop on the Internet at *http://frwebgate.access.gpo.gov/cgi-bin/leaving.cq* approximately 30 days after the workshop or at the Division of Dockets Management (see **ADDRESSES**), Monday through Friday between 9 a.m. and 4 p.m. You may also request a copy of the transcript from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

Dated: February 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–1371 Filed 2–10–06; 11:33 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D–1400]

Guidance for Industry: Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications,'' dated February 2006. The guidance is intended to provide sponsors with recommendations for the conduct of developmental toxicity studies for

investigational preventive and therapeutic vaccines for infectious disease indications. The recommendations pertain to the assessment of the developmental toxicity potential of preventive and therapeutic vaccines for infectious diseases indicated for females of childbearing potential and pregnant individuals. This guidance document finalizes the draft guidance entitled ''Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications,'' dated August 2000.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the 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*.

FOR FURTHER INFORMATION CONTACT: Astrid Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications,'' dated February 2006. The guidance document provides sponsors with recommendations for the conduct and assessment of developmental toxicity studies for investigational preventive and therapeutic vaccines for infectious diseases indicated for women of childbearing potential and pregnant women.

This guidance document finalizes the draft guidance entitled ''Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications,'' dated August 2000 (65 FR 54534, September 8, 2000). The guidance was revised based on public comments submitted to the Division of Dockets Management on the draft guidance, and on recommendations made by an expert panel convened at a workshop entitled ''Non-Clinical Safety Evaluation of Preventive Vaccines: Recent Advances and Regulatory Considerations'' held December 2 and 3, 2002, Arlington, VA.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance for 21 CFR 601.2 has been approved under OMB control number 0910–0338.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 1, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1998 Filed 2–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request, Fogarty International Center CareerTrac

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Fogarty International Center, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Fogarty International Center CareerTrac.

Type of Information Collection Request: NEW.

Need and Use of Information Collection: This data collection system is being developed to track, evaluate and report short and long-term output, outcomes and impacts of international trainees involved in health research training programs—specifically tracking this for at least ten years following training. The data collection system provides a streamlined, Web-based application permitting principal investigators to record career achievement progress by trainee on a voluntary basis. FIC Program Managers will use this data to monitor, evaluate and adjust grants to ensure desired outcomes are achieved, comply with OMB Part requirements for managing grants, respond to congressional inquiries, and as a guide to in future strategic and management decisions regarding the grants training program.

Frequency of Response: Annual and periodic.

Affected Public: none.

Type of Respondents: Principal Investigators funded by Fogarty International Center.

The annual reporting burden is as follows:

Estimated Number of Respondents: 150;

Estimated Number of Responses per Respondent: 15;

Average Burden Hours per Response: .50; and