

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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~~Centers for Disease Control and Protection~~

~~Food and Drug Administration~~

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[Docket No. 2006N-0065]

~~National Institute of Allergy and Infectious Diseases~~

Emerging Clostridial Disease; Public Workshop

AGENCY: ~~Centers for Disease Control and Prevention, HHS; Food and Drug Administration, HHS; National Institutes of Allergy and Infectious Diseases, HHS.~~

ACTION: Notice of public workshop; request for comments.

SUMMARY: <sup>on behalf of</sup> ~~The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institute of Allergy and Infectious Diseases (NIAID)~~ are announcing a public workshop entitled "Emerging Clostridial Disease." This public workshop is intended to develop a draft research agenda to better understand the virulence, pathogenesis, host factors, and nonantimicrobial risk factors contributing to reports of morbidity and mortality associated with *Clostridium sordellii* (*C. sordellii*) and *Clostridium difficile* (*C. difficile*). Additionally, our goals are to identify research needs and priorities that will enable rapid progress as well as to develop and provide recommendations for detecting cases and conducting surveillance of diseases and organisms.

DATES: The public workshop will be held on May 11, 2006, from 8:30 a.m. to 4:30 p.m. See section III of this document for information on how to register

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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](mailto: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: ~~cderecsec@fda.hhs.gov~~; *cderecsec@fda.hhs.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)

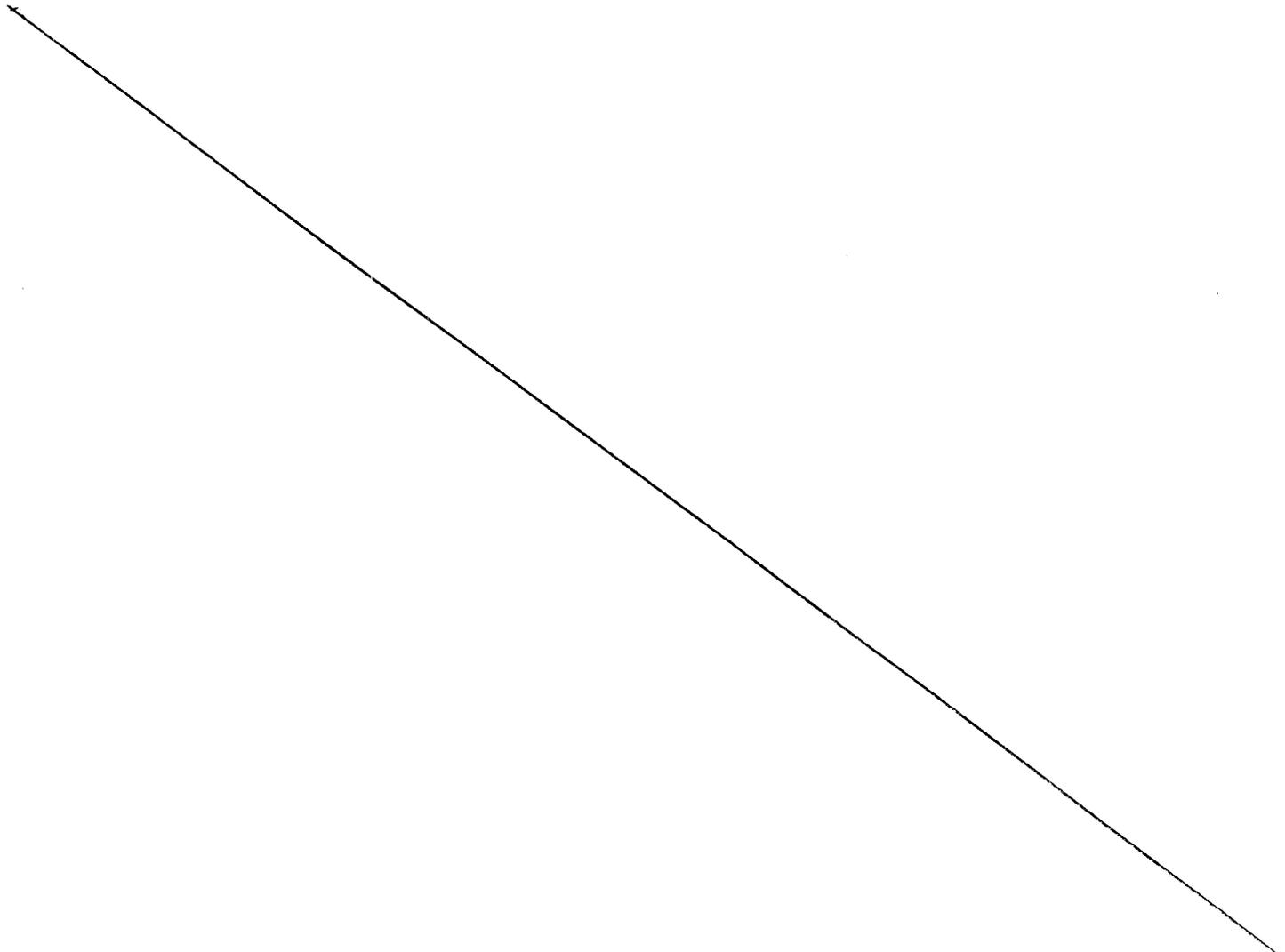
#### IV. How Should You Send Comments on the Issues?

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**).

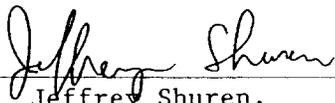
#### **V. Will Meeting Transcripts Be Available?**

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-????? Filed ??-??-06; 8:45 am]

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