

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0065]

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Commenter [Signature]

dwb

Emerging Clostridial Disease; Public Workshop; Reopening of the Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments; reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening until July 31, 2006, the administrative record to accept comments concerning the public workshop entitled "Emerging Clostridial Disease," as the administrative record officially closed on June 15, 2006.

DATES: Submit written or electronic comments by July 31, 2006.

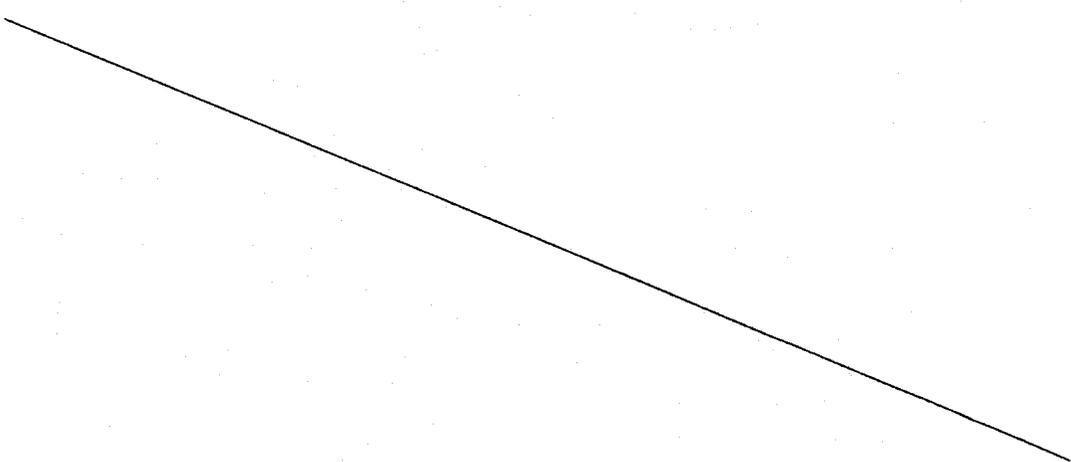
ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Lee Lemley, Center for Drug Evaluation and Research (HFD-006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5392.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 14, 2006 (71 FR 7778), FDA published a notice announcing a public workshop entitled "Emerging Clostridial Disease," to be held on May 11, 2006. This workshop was developed in response to reports of morbidity and mortality associated

with *Clostridium sordellii* (*C. sordellii*) and *Clostridium difficile* (*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 acquired *C. difficile* infection. The goal of the workshop was to bring together scientific and public health experts to develop a draft research agenda. Additionally, the goals were to identify research needs and priorities that will enable rapid progress in detecting cases and conducting surveillance of disease and organisms. Interested persons were asked to submit written comments by June 15, 2006. In the interest of allowing additional comments to be received, FDA has decided to reopen the comment period until July 31, 2006.

Interested persons may, on or before July 31, 2006, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this public workshop. 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.

Dated: 6/28/06

June 28, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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