

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anthrax Vaccines; Efficacy Testing and Surrogate Markers of Immunity; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), in cooperation with the Department of Defense (DoD), is announcing the following public workshop: “Anthrax Vaccines: Efficacy Testing and Surrogate Markers of Immunity.” The workshop will discuss possible strategies for the efficacy testing of investigational anthrax vaccines.

Date and Time: The public workshop will be held on April 23, 2002, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Jay P. Sanford Auditorium on the campus of the Uniformed Services University of Health Sciences (USUHS), 4301 Jones Bridge Rd., Bethesda, MD 20814.

Contact: Kerry Davis, Science Applications International Corp. (SAIC), 5340 Spectrum Dr., suite N, Frederick, MD 21703, 301-619-7078, FAX 301-698-6188, e-mail: kerry.davis@det.amedd.army.mil.

Registration: Preregistration is required and must be completed by April 12, 2002. Contact Kerry Davis (see “*Contact*” for address) for information about registration, including registration fees. Seating is limited.

If you need special accommodations due to a disability, please contact Kerry Davis at least 7 days in advance of the meeting.

Transcripts: You may request public workshop transcripts in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16,

Rockville, MD 20857. The transcripts will be available approximately 15 working days after the meeting at the cost of 10 cents per page. The public workshop transcript will also be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>

SUPPLEMENTARY INFORMATION: CBER, in cooperation with DoD, is holding a public workshop entitled “Anthrax Vaccines: Efficacy Testing and Surrogate Markers of Immunity.” The workshop will discuss: (1) Pathogenesis of *Bacillus anthracis*, (2) animal models of anthrax, (3) immunogenicity data available from human clinical trials of anthrax vaccines, and (4) identification

of surrogate markers and possible strategies. The workshop's goal is to expedite the development of anthrax vaccines by providing additional information about efficacy testing of these vaccines.

Dated: _____

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