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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Animal Models and Correlates of Protection for Plague Vaccines; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop: "Animal Models and Correlates of Protection for Plague Vaccines." The purpose of this workshop is to provide a public forum to discuss the animal models that may be most appropriate for evaluating new plague vaccines; the critical immune responses that may correlate with protection against plague; and the kinds of experimental and clinical assays that will need to be developed to measure these critical immune responses both in animals and in humans. The workshop will develop information that may be critical to the design of the pivotal studies required to assess plague vaccine efficacy.

Date and Time: This 1 1/2-day public workshop will be held on October 13, 2004, from 8:30 a.m. to 5 p.m., and October 14, 2004, from 8:30 a.m. to 12 noon.

Location: The workshop will be held at the Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD.

The Marriott Gaithersburg Washingtonian Center is located approximately 30 minutes from Ronald Reagan Washington National and Washington Dulles

International airports. Directions to the hotel can be found at <http://marriott.com/property/propertyPage/WASWG>.

Contact Person: Regarding the public workshop: Robert J. Watson, Science Applications International Corp., 5340 Spectrum Dr., suite N, Frederick, MD 21703, 301-228-3148, FAX: 301-698-5991, e-mail: robert.j.watson@saic.com.

Regarding this document: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

Registration: Registration is required; however, there is no registration fee for this public workshop. The deadline for registration is Wednesday, October 6, 2004. There will be no onsite registration. Information about the workshop and online registration can be found at <https://www.seeuthere.com/event/m2c640-122589588204>.

If you need special accommodations due to a disability, please contact Robert Watson (see *Contact Person*) at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: FDA's Center for Biologics Evaluation and Research; the National Institutes of Health, National Institute of Allergy and Infectious Diseases; and the Department of Health and Human Services, Office of Research Development and Coordination are sponsoring a public workshop. The workshop will be divided into interactive sessions in which leaders in the plague research field will present topics of particular relevance to plague vaccines. The sessions will include the following topics: (1) Introduction to the "Animal Rule," (2) pathogenesis of plague, (3) plague vaccines and assessment of immune responses, (4) human disease and relevant animal models, and (5) implementation of the "Animal Rule" for plague vaccines. In addition, an expert panel will discuss the issues that will be critical for the

development and eventual licensure of plague vaccines. The workshop's goal is to expedite the development and licensure of new plague vaccines by providing information critical to the development of the following: (1) Appropriate animal models, (2) immuno-assays, and (3) testing plans for vaccine evaluation.

Transcripts: Transcripts of the workshop may be requested in writing 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 workshop at a cost of 10 cents per page. Additionally,

the transcript will be placed on the FDA Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: 8/24/04
August 24, 2004.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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Joanne