DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Public Workshop on Burkholderia: Exploring Current Issues and Identifying Regulatory Science Gaps

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: ''Public Workshop on *Burkholderia:* Exploring Current Issues and Identifying Regulatory Science Gaps.'' An interagency planning committee led by FDA, in collaboration with the Defense Threat Reduction Agency; the National Institute of Allergy and Infectious Diseases, a component of the National Institutes of Health; the Centers for Disease Control and Prevention; the U.S. Army Medical Research Institute of Infectious Diseases; the Biomedical Advanced Research and Development Authority; the Chemical Biological Medical Systems Joint Project Management Office; the U.S. Strategic Command Center for Combating Weapons of Mass Destruction; and the Joint Science and Technology Office for Chemical and Biological Defense, developed this workshop to present the most current information on melioidosis (caused by *Burkholderia pseudomallei*) and glanders (caused by *B. mallei*), with the general purpose of building on information presented at previous meetings and identifying future areas of research needed to advance animal model development and to advance candidate medical countermeasures (MCMs) for approval, licensure, or clearance.

DATES: This public workshop will be held on Thursday, November 29, 2012, from 8 a.m. EST to 5 p.m. EST, and Friday, November 30, 2012, from 8 a.m. EST to 12 noon EST. Persons interested in attending the workshop in person or viewing via Webcast must register by Wednesday, November 21, 2012, at 5 p.m. EST.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

FOR FURTHER INFORMATION CONTACT: Pamela Chamberlain, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4122, 301–796–2968, FAX: 301–847–8615, email: *Pamela.Chamberlain@fda.hhs.gov,* Web site: *http://www.fda.gov/medicalcountermeasures.*

SUPPLEMENTARY INFORMATION:

I. Background

B. pseudomallei is a gram-negative bacterial pathogen that causes melioidosis, a disease endemic in Southeast Asia and northern Australia. Melioidosis is historically associated with a high mortality rate due to the speed with which septicemia develops and the inherent resistance of the bacteria to several classes of antibiotics. For example, a 20-year prospective study of melioidosis in northern Australia found an overall mortality of 14 percent and a 50 percent mortality rate for patients with septic shock (Ref. 1). A 9-year prospective study of melioidosis in northeast Thailand found an overall mortality rate of 42.6 percent (Ref. 2). Prolonged courses of antibiotics are required to treat melioidosis (Ref. 3). Despite prolonged antimicrobial therapy, recurrent disease is common (at a rate of greater than or equal to 6 percent in the first year) (Refs. 1 and 4). In addition to the public health threat posed by naturally occurring infections, *B. pseudomallei* has been determined to pose a material threat sufficient to affect the United States' national security (Ref. 5).

B. mallei (formerly *Pseudomonas mallei*) is a gram-negative, bacterial pathogen that causes glanders and is primarily a zoonotic disease in Africa, Asia, the Middle East, and Central/South America. Natural glanders infections occur primarily in horses, donkeys, and mules, but most mammals have some degree of susceptibility. While human susceptibility to *B. mallei* infection has not been studied indepth, the organism is highly infectious in the laboratory setting. Prolonged antimicrobial therapy is required to treat *B. mallei* infection and prevent its relapse (Refs. 6 and 7). *B. mallei* has also been determined to pose a material threat sufficient to affect the United States' national security (Ref. 5).

Because of the lengthy antibiotic therapy required to treat melioidosis and glanders and the suboptimal clinical outcomes, lack of vaccines, possible biothreat applications, and public health implications, there is significant interest in developing new MCMs as well as improved animal models to evaluate candidate MCMs for these diseases. This public workshop was designed with specific goals that include, but are not limited to:

- Review of the current state of the knowledge of human melioidosis and glanders;
- Discussion of the availability of relevant animal models and their current state of development;
- Discussion of the availability, development, procurement, and stockpiling of relevant MCMs, including diagnostic tests; and
- Identification of the scientific and regulatory considerations associated with testing and development of MCMs for safe and effective treatment or prevention of these diseases.

II. How to Register

If you wish to attend the public workshop or view via Webcast, you must register at *http://www.fda.gov/medicalcountermeasures* by Wednesday, November 21, 2012, at 5 p.m. EST. When registering, you must provide the following information: (1) Your name, (2) title, (3) company or organization (if applicable), (4) mailing address, (5) phone number, and (6) email address.

There is no fee to register for the public meeting and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited.

If you need special accommodations due to a disability, please enter pertinent information in the ''Notes'' section of the electronic registration form when you register.

III. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Currie B.J., L. Ward, and A.C. Cheng, ''The Epidemiology and Clinical Spectrum of Melioidosis: 540 Cases From the 20 Year Darwin Prospective Study,'' *Public Library of Science Neglected Tropical Diseases,* vol. 4(11):e900, 2010.

2. Limmathurotsakul D., S. Wongratanacheewin, N. Teerawattanasook, et al, ''Increasing Incidence of Human Melioidosis in Northeast Thailand,'' *American Journal of Tropical Medicine and Hygiene,* vol. 82(6), pp. 1113–1117, 2010.

3. Wiersinga W.J., B.J. Currie, and S.J. Peacock, ''Melioidosis,'' *The New England Journal of Medicine,* vol. 367(11), pp. 1035–1044, 2012.

4. Limmathurotsakul D., W. Chaowagul, W. Chierakul, et al., ''Risk Factors for Recurrent Melioidosis in Northeast Thailand,'' *Clinical Infectious Diseases,* vol. 43(8), pp. 979–986, 2006.

5. U.S. Department of Health and Human Services, ''2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy,'' (Washington, DC: U.S. Department of Health and Human Services, 2012), available at: *http://www.phe.gov/Preparedness/mcm/phemce/Documents/2012-PHEMCE-Strategy.pdf,* accessed October 16, 2012.

6. Srinivasan A., ''Glanders in a Military Research Microbiologist,'' *The New England Journal of Medicine,* vol. 345(4), pp. 256–258, 2001.

7. Gregory, B.C., and D.M. Waag, ''Glanders,'' in *Textbook of Military Medicine: Medical Aspects of Chemical and Biological Warfare* (Washington, DC: Office of the Surgeon General, 2007), available at: *https://ke.army.mil/bordeninstitute/published_volumes/biological_warfare/BW-ch06.pdf,* accessed October 16, 2012.

Dated: November 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on 15 August 2012 on page 48993 and allowed 60-days for public comment. 1 public comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

5 CFR 1320.5 (General requirements) Reporting and Recordkeeping Requirements: Final Rule requires that the agency inform the potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. This information is required to be stated in the 30-day **Federal Register** Notice.

Proposed Collection: Title: The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer. *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* This is to continue the Phase II follow-up of the Sister Study — a study of genetic and environmental risk factors for the development of breast cancer in a high-risk cohort of sisters of women who have had breast cancer. The etiology of breast cancer is complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. By focusing on genetically susceptible subgroups, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible. Sisters of women with breast cancer are one group at increased risk for breast cancer; we would expect at least 2 times as many breast cancers to accrue in a cohort of sisters as would accrue in a cohort identified through random sampling or other means. In addition, a cohort of sisters should be enriched with regard to the prevalence of relevant genes and/or exposures, further enhancing the ability to detect gene-environment interactions. Sisters of women with breast cancer will also be at increased risk for ovarian cancer and possibly for other hormonally-mediated diseases. From August 2003 through July 2009, we enrolled a cohort of 50,884 women who had not had breast cancer. We estimated that after the cohort was fully enrolled, approximately 300 new cases of breast cancer will be diagnosed during each year of follow-up. Thus far 1,634 participants have reported being diagnosed with breast cancer. *Frequency of Response:* For the remainder of the study, women will be contacted once each year (when not scheduled for ''triennial'') to update contact information and health status (10 minutes per response); and asked to complete short (75 minutes per response) follow-up interviews or questionnaires (''triennial'') every three years. Follow-up and validation of reported incident breast cancer and other health outcomes is conducted under Clinical Exemption CE 2009–09–004. *Affected Public:* Study participants, next-of-kin/proxies. *Type of Respondents:* Participants enrolled in high-risk cohort study of risk factors for breast cancer; next-of-kin/proxies. The annual reporting burden is as follows: *Estimated Number of Respondents:* 50,884 study participants or next-of-kin/proxies. *Estimated Number of Responses per Respondent:* See annualized table below:

ESTIMATED ANNUALIZED BURDEN HOURS

Activity	Estimated number of respondents	Estimated responses per respondent	Average burden hours per response	Estimated total burden hours requested
Annual Updates	33,923	1	10/60	5,654
Follow-Up II (triennial)	16,961	1	1.25	21,202
Total				26,856

Average Burden Hours Per Response: 42 minutes; and *Estimated Total Annual Burden Hours Requested:* 26,856. The estimated total annualized cost to respondents $537,120 (assuming $20 hourly wage × 26,856). There are no capital, operating, or maintenance costs.

Request For Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the