(arthropod-borne viruses), by transfusion, infusion, implantation, or transplantation in the United States. The public workshop will feature presentations and roundtable discussions led by experts from academic institutions, government, and industry.

Date and Time: The public workshop will be held on December 14, 2009, from 8:30 a.m. to 5:30 p.m. and December 15, 2009, from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Natcher Conference Center, Main Auditorium, Bldg. 45, National Institutes of Health, 8800 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, suite 550N, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *rhonda.dawson@fda.hhs.gov*.

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the *Contact Person* by November 20, 2009. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

Requests for Presentations of Data: Interested persons are invited to present data related to technologies for the detection or inactivation of arboviruses in blood products, organs, or tissues. If you are interested in presenting, submit a brief statement of the general nature of the presentation to the *Contact Person* by November 20, 2009 (see section II of this document for additional information).

SUPPLEMENTARY INFORMATION:

I. Background

Arboviruses are a large group of viruses that are spread by certain invertebrate animals, most commonly blood-sucking insects. Arboviruses are found throughout the world, including the United States. Arboviruses, such as Dengue virus, Japanese Encephalitis virus (JE), tick-borne encephalitis virus (TBE), and West Nile virus (WNV), are becoming increasingly widespread. Transmission of WNV and Dengue virus through blood transfusion has been well documented. Transfusion transmission of the Colorado tick fever (CTF) virus, a tick-borne agent present in the United States, also has been reported. Other arboviruses, including JE, TBE, and St. Louis Encephalitis are of concern to blood, cell, tissue, and organ safety because of the possibility of viremia in asymptomatic human infections. Dengue outbreaks have recently occurred in Texas, Hawaii, Puerto Rico, and the U.S. Virgin Islands. Dengue virus, as well as TBE, and JE, have the potential to become endemic in certain regions of the United States. Therefore, proactive discussions among the Department of Health and Human Services public health agencies, including the FDA, National Institutes of Health, and the Centers for Disease Control and Prevention, academia, industry, blood establishments, cell and tissue establishments, and other stakeholders are necessary to address blood, cell, tissue, and organ safety in response to the emerging arboviruses.

The public workshop will facilitate a scientific discussion on approaches to reduce the risk of transmission of arboviruses by transfusion, infusion, implantation, or transplantation in the United States. Topics to be discussed include: (1) Biology and pathogenesis of arboviruses; (2) epidemiology and prevention of arbovirus vectors and hosts in the United States; (3) laboratory detection and prevention of arbovirus infection in humans; (4) transfusion, infusion, implantation or transplantation transmission of arboviruses in the United States; and (5) potential approaches, including donor testing and pathogen inactivation, to reduce the risk of transfusion transmission of arboviruses.

II. Requests for Presentations of Data

Interested persons are invited to present data related to technologies for the detection or inactivation of arboviruses in blood products, organs, or tissues. Those desiring to make presentations at the workshop should notify the *Contact Person* and submit a brief statement of the general nature of the presentation before November 20, 2009. Presentations will be scheduled on the afternoon of December 15, 2009. Time allotted for each presentation will be limited depending on the number of individuals requesting to speak.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.*

Dated: October 22, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25802 Filed 10–26–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0063] (formerly Docket No. 2004N–0346)

Saccharomyces boulardii Eligibility for Consideration To Be Added to the Over-the-Counter Drug Monograph for Antidiarrheal Drug Products; Request for Safety and Effectiveness Data; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Withdrawal of notice of eligibility and request for data and information.

SUMMARY: We (Food and Drug Administration (FDA)) are withdrawing a notice of eligibility and call-for-data for safety and effectiveness information. The original notice published in the **Federal Register** of August 23, 2004 (69 FR 51852). In that notice, we announced that *Saccharomyces boulardii* (*S. boulardii*) was eligible for consideration to be added to the over-the-counter (OTC) monograph for antidiarrheal drug products.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5411, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION: In 2004, we published a notice of eligibility for consideration of the yeast *S. boulardii* in the OTC drug monograph system. We announced our intention to evaluate *S. boulardii* for inclusion in the monograph for OTC antidiarrheal drug products (21 CFR part 335). The notice also requested submission of data and information on the safety and effectiveness of *S. boulardii* for us to determine whether it could be generally recognized as safe and effective (GRAS/E) and not misbranded for its proposed OTC drug use.

S. boulardii for antidiarrheal use meets the definition of a drug in the Federal Food, Drug, and Cosmetic Act.

(See section 201(g)(1) (21 U.S.C. 321(g)(1).) *S. boulardii* is a yeast or unicellular fungus and, therefore, also meets the definition of a biological product in the Public Health Service Act for this use. (See section 351(i) (42 U.S.C. 262(i) and 21 CFR 600.3(h)(1).) We have determined that this yeast is more appropriately regulated as a biological product under the biologics license application system than as an OTC drug product under the monograph system. Because we have decided to regulate *S. boulardii* as a biological product, *S. boulardii* is not eligible for consideration to be included in an OTC drug monograph. Therefore, this document withdraws the 2004 notice of eligibility permitting consideration of *S. boulardii* for addition to the monograph for OTC antidiarrheal drug products. This document also withdraws our 2004 request for submission of safety and effectiveness data and information on *S. boulardii* for OTC antidiarrheal use. Any further consideration of the potential therapeutic use(s) of this yeast should be addressed under regulations and procedures governing biological products.

Dated: October 22, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25803 Filed 10–26–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2009–0091]

Notice of Availability of Proposed Guidance for Protecting Responders' Health During the First Week Following a Wide-Area Anthrax Attack

AGENCY: Office of Health Affairs, DHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Homeland Security (DHS) is accepting comments on ''Proposed Guidance for Protecting Responders' Health During the First Week Following a Wide-Area Anthrax Attack.''

DATES: Comments must be received by November 27, 2009.

ADDRESSES: Comments must be identified by docket number DHS–2009–0091 and may be submitted by one of the following methods:

- Mail: David V. Adams, U.S. Department of Homeland Security, Office of Health Affairs, Mail Stop 0315, Washington, DC 20528; and
- Federal Rulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Please note the Proposed Guidance is not a rulemaking and the Federal Rulemaking Portal is being utilized only as a mechanism for receiving comments.

FOR FURTHER INFORMATION CONTACT: David V. Adams, Director, Contingency Planning & Policy, Office of Health Affairs, Mail Stop 0315, Washington, DC 20528, e-mail address *david.v.adams@dhs.gov,* telephone number (202) 254–5756.

SUPPLEMENTARY INFORMATION:

I. Public Participation

DHS invites interested persons to contribute suggestions and comments on the document entitled ''Proposed Guidance for Protecting Responders' Health During the First Week Following a Wide-Area Anthrax Attack'' (Proposed Guidance) by submitting written data or views. Comments that will provide the most assistance to DHS will explain the reason for any recommended changes to the Proposed Guidance and include data, information, or authority that supports such recommended changes. DHS requests that commenters identify any recommended changes by page and line number, and/or by Figure or Table number. The Proposed Guidance can be viewed or downloaded at *http://www.regulations.gov.*

Instructions: All submissions received must include the agency/organization name and docket number for this action. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available on the Privacy and Use Notice link on the Administration Navigation Bar of *www.regulations.gov.*

You may submit your comments and material by the methods specified in the **ADDRESSES** section above. Please submit your comments and any supporting material by only one means to avoid the receipt and review of duplicate submissions. If you submit comments by mail, your submission should be an unbound document and no larger than 8.5 by 11 inches to enable copying and electronic document management.

Docket: The Guidance and any comments received can be viewed at *http://www.regulations.gov* by searching the docket number referenced above.

II. Background

This document provides policy recommendations for protection of the health of personnel responding to a wide-area anthrax attack. At the request of the Homeland Security Council (HSC) a Federal interagency working group, consisting of subject matter experts in biodefense, infectious diseases, and occupational health and safety, has developed this consensus proposed guidance regarding appropriate protective measures for responders in the immediate post-attack environment of an aerosolized anthrax attack. This proposed guidance statement reflects the most current understanding of the unique environment that will exist after a wide-area anthrax release. These recommendations will evolve with stakeholder input, scientific developments, and availability of new environmental monitoring techniques.

The Proposed Guidance does not have the force or effect of law.

DHS seeks comment on the Proposed Guidance document, which is available online at *http://www.regulations.gov.* Based on the comments received, DHS may make appropriate revisions to the Proposed Guidance or may leave the Proposed Guidance as is. In any event, DHS will make available the Final Guidance at *http://www.regulations.gov.* The Final Guidance will not have the force or effect of law.

Dated: October 21, 2009.

Alex Garza,

Assistant Secretary and Chief Medical Officer, Office of Health Affairs.

[FR Doc. E9–25770 Filed 10–26–09; 8:45 am]

BILLING CODE 9110–9K–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2004–19147]

Intent To Request Renewal From OMB of One Current Public Collection of Information: Flight Training for Aliens and Other Designated Individuals; Security Awareness Training for Flight School Employees

AGENCY: Transportation Security Administration, DHS.

ACTION: 60-day notice.

SUMMARY: The Transportation Security Administration (TSA) invites public comment on an existing information collection requirement abstracted below that will be submitted to the Office of Management and Budget (OMB) for renewal in compliance with the Paperwork Reduction Act. The collection involves conducting background checks for all aliens and other designated individuals seeking