

(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.

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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.

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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