

(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]

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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

flight instruction ("candidates") from Federal Aviation Administration (FAA)-certificated flight training providers. Through the information collected, TSA will determine whether a candidate is a threat to aviation or national security, and thus prohibited from receiving flight training or recurrent training. Additionally, flight training providers are required to conduct a security awareness program for their employees, and to maintain records associated with this training.

DATES: Send your comments by December 28, 2009.

ADDRESSES: Comments may be e-mailed to TSAPRA@dhs.gov or delivered to the TSA Paperwork Reduction Act (PRA) Officer, Office of Information Technology (OIT), TSA-40, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598-6040.

FOR FURTHER INFORMATION CONTACT: Ginger LeMay at the above address, or by telephone (571) 227-3616.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The Information Collection Requirement (ICR) documentation is available at <http://www.reginfo.gov>. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

OMB Number 1652-0021; Flight Training for Aliens and Other Designated Individuals; Security Awareness Training for Flight School Employees, 49 CFR Part 1552

This is a renewal information collection request that includes

background checks and fee changes for alien students requesting flight training in the United States.

Pursuant to 49 U.S.C. 44936 and 6 U.S.C. 469, TSA is required to conduct background checks for all aliens and other designated individuals seeking flight instruction with Federal Aviation Administration (FAA)-certificated flight training providers. In September 2004, TSA developed and implemented these requirements at 49 CFR part 1552, prescribing standards relating to the security threat assessment process that TSA conducts to determine whether candidates are a threat to aviation or national security and thus prohibited from receiving flight training. TSA published a notice prescribing the process to determine that an alien who takes recurrent flight training is not a risk to aviation or national security, and to impose reasonable fees for this process.¹

The collection of information required under 49 CFR part 1552 and the Appropriations Act of 2009 permits TSA to gather candidates' biographic information, which is used to perform background checks. Flight training candidates also have to submit fingerprint information for background checks. Additionally, flight training providers are required to conduct security awareness training for their employees to increase awareness of suspicious circumstances and activities of individuals enrolling in, or attending, flight training. The flight training provider may use the initial security awareness training program offered by TSA or an alternative initial training program offered by a third party, or training designed by the flight training provider itself. Each flight training provider employee must receive recurrent security awareness training each year, and flight training providers must maintain records of the training completed throughout the course of the individual's employment, and for one year after the individual is no longer a flight training provider employee.

Based on the numbers of respondents to date, TSA estimates a total of 31,000 respondents annually: 26,500 candidates and 4,500 registered flight training providers. Respondents are required to provide the subject information every time an alien or other

designated individual applies for pilot training as described in the regulation, which is estimated to be twice a year per candidate, for a total of 53,000 responses per year.

TSA estimates that it will take the 26,500 candidates 45 minutes per application (twice per year) to provide TSA with all of the information required, for a total approximate application burden of 39,750 hours per year. Flight training providers must keep records for five years from the time they are created, and it is estimated each of the 4,500 flight training providers will carry an annual recordkeeping burden of 104 hours, for a total of 468,000 hours. Thus, TSA estimates the combined hour burden associated with this collection to be 507,750 hours annually.

TSA estimates an annual cost burden of \$223 per application (an increase of 3% per year when compared to the \$205 per application cost burden that was estimated in 2004). The annual cost burden of \$223 includes a security fee of \$130, for a total annual burden of \$5,575,000 (12,500 Category 1-3 paying candidates × \$223 per application × twice per year application). Recurrent training candidates pay a fee of \$70 for a total of \$1,960,000 (14,000 recurrent training candidates × \$70 per application × twice per year application).

TSA estimates the yearly recordkeeping costs per flight training provider for retaining records of candidates' applications and its employees' security awareness training files is estimated to remain the same per record as previously estimated at \$1,500 for a total annual cost burden of 6,750,000 million (\$1,500 × 4,500). TSA estimates the recordkeeping cost burden for flight training providers that do not register with TSA is negligible.

The current combined annual cost burden to all respondents associated with this collection is estimated to be \$14,285,000 annually. The cost adjustments to TSA's original estimate are based on the added cost of 14,000 Category 4 recurrent training candidates estimated to apply for training twice per year; and the increase in the number of flight training providers from 3,000 to 4,500 who are subject to 49 CFR part 1552.

Issued in Arlington, VA, on October 21, 2009.

Ginger LeMay,
TSA Paperwork Reduction Act Officer, Office of Information Technology.

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¹ In September 2008, Congress passed the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (Appropriations Act of 2009), which amends 6 U.S.C. 469 and authorizes TSA to establish a process to determine that an alien who takes a recurrent flight training is not a risk to aviation or national security, and to impose reasonable fees for this process.