

Based on such a determination, the Secretary of Health and Human Services may declare an emergency that justifies the authorization of a product that is not otherwise approved, licensed or cleared for commercial use (“unapproved product”) or is not approved, licensed, or cleared for a particular use (“unapproved use of an approved product”). Following that declaration, the Commissioner of the Food and Drug Administration (FDA) may issue an Emergency Use Authorization (EUA).

The Biomedical Advanced Research and Development Authority (BARDA) of the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) has requested that FDA issue an EUA for doxycycline hyclate tablets accompanied by emergency use information for use by eligible USPS participants in the CRI and their household members. Doxycycline hyclate tablets are approved by the FDA for the post-exposure prophylaxis of anthrax. However, the doxycycline hyclate tablets for which BARDA seeks an EUA would be accompanied by emergency use information that is not included in any of the approved applications for doxycycline hyclate tablets. For this reason, an EUA is necessary. The September 23, 2008 determination by the Secretary of Homeland Security that there is a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *Bacillus anthracis*, and the October 1, 2008 declaration by the Secretary of Health and Human Services based on that determination that there is an emergency justifying the authorization of emergency use of doxycycline hyclate tablets accompanied by emergency use information, enables the FDA Commissioner to issue an EUA for doxycycline hyclate tablet emergency kits under section 564(a) of the FFDCA, 21 U.S.C. 360bbb–3(a).

With issuance of the EUA, eligible letter carriers participating in the CRI may receive the doxycycline hyclate tablet emergency kits, if not medically contraindicated, for future use by them and other members of their households during an anthrax emergency, subject to the terms of the authorization. The antibiotics and accompanying information may help protect these letter carriers and household members against contracting anthrax if, following an outdoor anthrax attack, the USPS is called upon to deliver the same or similar antibiotics to homes across their community where people may have

been exposed to *Bacillus anthracis*. In an anthrax attack, time is of the essence in preventing illness and death by getting antibiotics to people who may have been exposed. By providing advance protection to letter carriers who willingly put themselves at risk by delivering antibiotics in an affected community, the unique capabilities of the USPS may be used to get antibiotics to those who need them quickly.

The USPS initiative and EUA are one part of the Federal Government’s strategy to encourage preparedness at all levels of government to enable the nation to respond effectively in the event of an anthrax emergency.

II. Determination of the Secretary of Homeland Security

On September 23, 2008, pursuant to section 564(b)(1)(A) of the FFDCA, 21 U.S.C. 360bbb–3(b)(1)(A), the Secretary of Homeland Security determined that there is a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *Bacillus anthracis*. The Secretary of Homeland Security made this determination in a September 23, 2008 memorandum addressed to the Secretary of Health and Human Services. In that memorandum, the Secretary of Homeland Security stated that there is not currently a domestic emergency involving anthrax, there is not currently a heightened risk of an anthrax attack, and his Department has no credible information indicating an imminent threat of an attack involving *Bacillus anthracis*.

The Secretary of Homeland Security determined that there is a significant potential for a domestic emergency, involving a heightened risk of attack with *Bacillus anthracis*, on two bases: (1) The Department of Homeland Security has already found that an anthrax attack poses a material threat to the United States population sufficient to affect national security, which allows the Secretary to conclude that there is a non-negligible possibility that a heightened risk of attack will arise. The finding that an anthrax attack poses a material threat to the United States population sufficient to affect national security was made on January 20, 2004 regarding anthrax, and on September 22, 2006 regarding multi-drug resistant *Bacillus anthracis*, pursuant to section 319F–2(c)(2) of the Public Health Service (PHS) Act, 42 U.S.C. 247d–6b(c)(2). (2) Were the government to determine in the future that there is a heightened risk of an anthrax attack—if, for example, there were credible

information about an imminent threat of such an attack—that would almost certainly result in a domestic emergency. That is so, among other important reasons, because those exposed to *Bacillus anthracis* need to take appropriate antimicrobials rapidly after exposure to avoid contracting anthrax and because of the significant challenges to rapidly delivering such antimicrobials to those at risk in an anthrax emergency.

Given his determination that there is a significant potential for a domestic emergency, the Secretary of Homeland Security also urged the Secretary of Health and Human Services to employ all relevant emergency powers under section 564 of the FFDCA to ensure distribution of pre-need countermeasures that may be effective in preventing the contracting of anthrax by people in the delivery chain, such as USPS workers; first responders, including law enforcement; to essential government and non-government workers; and to the general public.

III. Declaration of the Secretary of Health and Human Services

On September 23, 2008, the Secretary of the Department of Homeland Security determined that there is a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *Bacillus anthracis*. Pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb–3(b), and on the basis of such determination, on October 1, 2008, I declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a).

Dated: October 1, 2008.

Michael O. Leavitt,
Secretary.

[FR Doc. E8–23544 Filed 10–1–08; 4:15 pm]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS) Executive Subcommittee.

Time and Date:

October 14, 2008, 1 p.m.–5 p.m.

October 15, 2008, 8:30 a.m.–4:30 p.m.

Place: Radisson Hotel Reagan National Airport, 2020 Jefferson Davis Hwy, Arlington, VA 22202.

Status: Open.

Purpose: The NCVHS Executive Subcommittee will hold a day and a half meeting to review the past year's accomplishments and conduct strategic planning for the coming year. On the afternoon of the first day, the Executive Subcommittee will review their 2008 activities, update operational work plans, and review Committee objectives and strategic plan for future NCVHS directions. On the second day the Subcommittee will continue strategic planning for future NCVHS directions, discuss collaborative activities with the Board of Scientific Counselors at the National Center for Health Statistics, the plans for updating the 21st Century Health Statistics, and the upcoming NCVHS 60th anniversary.

Contact Person for More Information:

Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS Web site: <http://www.ncvhs.hhs.gov/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: September 29, 2008.

James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. E8–23438 Filed 10–3–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS) Standards Subcommittee.

Time and Date: October 14, 2008 8:30 a.m.–12 p.m.

Place: Radisson Hotel Reagan National Airport, 2020 Jefferson Davis Hwy., Arlington, VA 22202.

Status: Open.

Purpose: The NCVHS Standards Subcommittee will hold a half day meeting to plan and discuss upcoming topics for hearings and recommendations.

Contact Person for More Information:

Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Denise Buenning, lead staff for Standards Subcommittee, NCVHS, Centers for Medicare and Medicaid Services, Office of E-Health Standards and Services, 7500 Security Boulevard, Room S2–26–17, Baltimore, Maryland 21244, telephone (410) 786–6711; or Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245. Further information also is available on the NCVHS home page: <http://www.ncvhs.hhs.gov/>, where an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: September 30, 2008.

James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. E8–23532 Filed 10–3–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Re-Designation of Head Start Grantees

AGENCY: U.S. Department of Health and Human Services.

ACTION: Notice; Federal Advisory Committee Act Meetings Announcement.

SUMMARY: Pursuant to Public Law 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the third meeting of the Secretary's Advisory Committee on Re-designation of Head Start Grantees, Department of Health and Human Services (HHS). The meeting will be held on Tuesday, October 21, 2008, from 9 a.m. to 5:30 p.m., and on Wednesday, October 22, 2008, from 9 a.m. to 1 p.m. at the Hotel Palomar Arlington, 1121 North 19th Street, in Arlington, Virginia. The meeting will be open to the public; however, seating is limited and preregistration is encouraged (see below).

FOR FURTHER INFORMATION CONTACT: Colleen Rathgeb, Office of Head Start, e-mail colleen.rathgeb@acf.hhs.gov or (202) 205–7378.

SUPPLEMENTARY INFORMATION: The Improving Head Start for School Readiness Act of 2007 (Pub. L. 110–134, Section 641(c)(2) [42 U.S.C. 9836]) requires the Secretary to develop a system for designation renewal to determine if Head Start agencies are delivering high-quality and comprehensive Head Start programs that meet the educational, health, nutritional, and social needs of the children and families they serve, and meet program and financial management requirements and the program performance standards. The Advisory Committee on Re-Designation of Head Start Grantees will provide advice and recommendations on the development of a transparent, reliable and valid system for designation renewal as required under the statute.

The third meeting of the Advisory Committee will be held on October 21–22, 2008, at the Hotel Palomar Arlington, which is located at 1121 North 19th Street, in Arlington, Virginia, one block from the Rosslyn Metro station. The Advisory Committee will review the results of the data analyses it requested from the Office of Head Start at its June meeting, discuss recommendations, and review a draft report. The meeting will be open to the public; however, seating is limited and preregistration is encouraged. To preregister, please e-mail AdvisoryCommittee@pal-tech.com with "Meeting Registration" in the subject line, or call Tara Nordlander at 703–243–0495 by 5 p.m. EST, October 17, 2008. Registration must include your name, affiliation, phone number, and days attending. If you require a sign language interpreter or other special assistance, please call Tara Nordlander at 703–243–0495 as soon as possible and no later than October 10, 2008.

Written comments may be submitted electronically to AdvisoryCommittee@pal-tech.com with "Public Comment" in the subject line. HHS recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment, and it allows HHS to contact you if further information on the substance of the comment is needed or if your comment cannot be read because of technical difficulties. HHS's policy is that HHS will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment placed in the official public record. If HHS cannot read your comment because of technical difficulties and cannot