a federal declaration in support of an emergency use authorization under section 564 of the FDCA unless such declaration specifies otherwise.

This first day of October, 2008.

Michael O. Leavitt,

Secretary of Health and Human Services.

APPENDIX I—LIST OF U.S. GOVERNMENT CONTRACTS

Contract	Manufacturer	Covered countermeasure	PL 85–804 coverage*
HHSO100200500007C	Cangene	Anthrax immune globulin—AIG	No.
HHSO100200500006C	HGS	Anthrax monoclonal antibody-ABThrax	No.
HHSO100200600019C	Emergent Biodefense Operations	BioThrax (Anthrax Vaccine Adsorbed, AVA)	Yes.
HHSO100200700037C	Emergent Biodefense Operations	BioThrax (Anthrax Vaccine Adsorbed, AVA)	No.
W9113M–04–D–0002	BioPort (Emergent Biosolutions)	BioThrax (Anthrax Vaccine Adsorbed, AVA)	Yes.
DAMD 17–97–D–00003	BioPort (Emergent Biosolutions)	BioThrax (Anthrax Vaccine Adsorbed, AVA) Shipping.	Yes.
HHSN 272200700035C	Elusys	Anthrax monoclonal antibody—ETI–204	No.
HHSN 272200700033C	Pharmathene	Anthrax monoclonal antibody—Valortim	No.
HHSN 272200700034C	Emergent BioSolutions	Anthrax immune globulin—AIG	No.
NO1–A1–30052	Avecia (Pharmathene)	Recombinant protective antigen (rPA) anthrax vaccine.	No.
V797P–5777x	Shering Corp.	Cipro 250mg/5ml; 100ml suspension	No.
V797P–5977x	Cobalt Pharmaceuticals	Cipro 500mg tablets	No.
V797P–5941x	Blu Pharmaceuticals	Doxycycline 100mg tablets	No.
V797P–5883x	Pfizer, Inc	Doxycycline 25mg/5ml suspension 60ml	No.
V797P–5669x	Abraxis Bioscience, Inc	Doxycycline 100mg vial IV	No.
V797–DSNS–8002	Sandoz, Inc	Amoxicillin 500mg capsules	No.
V797–DSNS–8002	Sandoz, Inc	Amoxicillin 400mg/5ml; 100ml suspension	No.
V797BPA0015	Bedford Labs	Rifampin 600mg vial IV	No.
V797P–5396x	Hospira	Clindamycin 150mg/ml 6ml vial IV	No.
V797P–5669x	Abraxis Bioscience, Inc	Vancomycin 1 g vial IV	No.
V797P–1020x	McKesson	Penicillin GK 20 million unit vial IV	No.
V797P–5387x	Johnson and Johnson Healthcare	Levofloxacin 5mg/ml 150ml bag IV	No.

*Status of indemnification coverage under P.L. 85–804 (An Act to authorize the making, amendment and modification of contracts to facilitate the national defense.)

[FR Doc. E8–23547 Filed 10–1–08; 4:15 pm]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Determination and Declaration Regarding Emergency Use of Doxycycline Hyclate Tablets Accompanied by Emergency Use Information

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Notice.

SUMMARY: The Secretary of the Department of Health and Human Services (HHS) is issuing this notice pursuant to section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 360bbb–3(b)(4), to justify the emergency use of doxycycline hyclate tablets accompanied by emergency use information, contained in emergency kits for eligible United States Postal Service (USPS) Cities Readiness Initiative (CRI) participants and their household members in advance of a potential attack involving *Bacillus anthracis. Bacillus anthracis* is a biological agent known to cause anthrax. The Secretary, HHS, provides notice of the determination of the Secretary of Homeland Security on September 23, 2008 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,* although there is no current domestic emergency involving anthrax, no current heightened risk of an anthrax attack, and no credible information indicating an imminent threat of an attack involving *Bacillus anthracis.* The Secretary also provides notice that, on the basis of such determination, he has declared an emergency justifying the authorization of emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued by the Food and Drug Commissioner under 21 U.S.C. 360bbb–3(a).

DATES: This Notice and referenced HHS declaration are effective as of October 1, 2008.

FOR FURTHER INFORMATION CONTACT: RADM W.C. Vanderwagen, M.D., Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

The CRI, begun in 2004, is a federally supported effort to prepare 72 major U.S. metropolitan areas to effectively respond to a large-scale bioterrorist event by dispensing antibiotics to their entire identified population within 48 hours of the decision to do so. Over the past several years, HHS and the USPS have developed and tested in three U.S. cities—Seattle, Philadelphia and Boston—the ability of letter carriers to quickly deliver door-to-door a few days' worth of antibiotics to residential addresses. This quick-strike capability is intended to buy time for State and local public health authorities to set up points of dispensing for further provision of antibiotics across the community, as needed.

Under Section 564 of the FFDCA, the Secretary of Homeland Security may determine that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological chemical, radiological or nuclear agent or agents.

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. Doxycyline 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 doxyclycline 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 doxycyline 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]

BILLING CODE 4150–37–P

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.