DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a meeting by conference call. The meeting is open to the public.

DATES: The meeting will be held on May 11, 2007, from 1 p.m. to 2:30 p.m.

ADDRESSES: This meeting will be held by conference call.

FOR FURTHER INFORMATION CONTACT: Ms. Emma English, Program Analyst, National Vaccine Program Office, Department of Health and Human Services, Room 443–H Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; (202) 690–5566, *nvpo@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Service Act (42 U.S.C. Section 300aa–1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Assistant Secretary for Health, as the Director of the National Vaccine Program, on matters related to the program's responsibilities.

This is a special meeting of the NVAC. Discussions will surround a draft document titled ''The Promise and Challenge of Adolescent Immunization,'' prepared at the request of the Assistant Secretary for Health by the Committee's Adolescent Immunization Working Group. The Committee will review the draft document and the Committee will vote to either endorse the document as an official NVAC report or request that further revisions be made to the document by the Working Group. A copy of this draft document can be found on the World Wide Web (*http://www.hhs.gov/nvpo*) or by contacting the contact person identified above.

For this special meeting, remote participation will be made available via a toll-free call-in phone number. This call-in number can be obtained from the contact person identified above and will be operator assisted to provide members of the public the opportunity to provide comments to the Committees. Members of the public will have the opportunity to provide comments at the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed written comment made available to the Committee members should submit materials to the Executive Secretary, NVAC, through the contact person listed above prior to close of business May 7, 2007. Any written materials submitted by the public that are to be discussed by the Committee will be made available via the World Wide Web (*http://www.hhs.gov/nvpo*) prior to the meeting.

Dated: April 17, 2007.

Raymond Strikas,

Medical Advisor, National Vaccine Program Office.

[FR Doc. E7–7682 Filed 4–20–07; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Preparedness and Response; HHS Public Health Emergency Medical Countermeasures Enterprise Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats

AGENCY: Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

ACTION: Notice.

SUMMARY: The United States faces serious public health threats from the deliberate use of weapons of mass destruction (WMD)—chemical, biological, radiological, or nuclear (CBRN)—by hostile States or terrorists, and from naturally emerging infectious diseases that have a potential to cause illness on a scale that could adversely impact national security. Effective strategies to prevent, mitigate, and treat the consequences of CBRN threats is an integral component of our national security strategy. To that end, the United States must be able to rapidly develop, stockpile, and deploy effective medical countermeasures to protect the American people. The HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) has taken a holistic, end-to-end approach that considers multiple aspects of the medical countermeasures mission including research, development, acquisition, storage, maintenance, deployment, and guidance for utilization. Phase one of this approach established the *HHS PHEMCE Strategy for Chemical, Biological, Radiological, and Nuclear Threats (HHS PHEMCE Strategy).* The HHS PHEMCE Strategy, published in the **Federal Register** on March 20, 2007, described a framework of strategic policy goals and objectives for identifying medical countermeasure requirements and establishing priorities for medical countermeasure evaluation, development and acquisition. These strategic policy goals and objectives were used to establish the Four Pillars upon which this *HHS Public Health Emergency Medical Countermeasures Enterprise Implementation Plan (HHS PHEMCE Implementation Plan)* is based. The *HHS PHEMCE Implementation Plan* considers the full spectrum of medical countermeasures-related activities, including research, development, acquisition, storage/maintenance, deployment, and utilization. The *HHS PHEMCE Implementation Plan* is consistent with the President's *Biodefense for the 21st Century* and is aligned with the National Strategy for *Medical Countermeasures against Weapons of Mass Destruction.*

DATES: This notice is effective as of April 16, 2007.

FOR FURTHER INFORMATION CONTACT: Dr. Susan Coller, Policy Analyst, Office of Public Health Emergency Medical Countermeasures, Office of the Assistant Secretary for Preparedness and Response at 330 Independence Ave., SW., Room G640, Washington, DC 20201 or by phone 202–260–1200.

HHS PHEMCE Approach to Medical Countermeasures

The United States faces serious public health threats from the deliberate use of chemical, biological, radiological, or nuclear (CBRN) threat agents by hostile states or terrorists, and from naturally emerging infectious diseases that have the potential to cause illness on a scale that would impact national security. Within the Federal government, the mission of the Department of Health and Human Services (HHS) is to protect the civilian population by providing leadership in research, development, acquisition, deployment, and guidance for effective use of medical countermeasures for mitigation of CBRN events. This key role was identified in the *National Strategy to Combat Weapons of Mass*

Destruction,[1] *Biodefense for the 21st Century*,[2] and the National Strategy for *Medical Countermeasures against Weapons of Mass Destruction*,[3] which together comprise the national blueprint for addressing CBRN defense.

The HHS Public Health Emergency Medical Countermeasures Enterprise (HHS PHEMCE) leads the mission to develop and acquire medical countermeasures that will improve public health emergency preparedness as well as prevent and mitigate the adverse health consequences associated with CBRN and naturally occurring threats. HHS PHEMCE is a coordinated, intra-agency effort led by the Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes three HHS internal agencies: The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). Additionally, HHS PHEMCE collaborates with its *ex officio* members: The Department of Defense (DOD), the Department of Homeland Security (DHS), the Department of Veterans Affairs (VA) and other interagency stakeholders as appropriate.

The *HHS PHEMCE Implementation Plan for CBRN Threats* addresses twelve biological threat agents, a class of chemical threats (volatile nerve agents) and radiological and nuclear threats. The medical countermeasure programs described will involve the full range of activities from research through advanced development, acquisition, storage, maintenance, deployment and utilization and will include all of the PHEMCE. However, the detailed focus of this Plan will be on the acquisition phase using the remaining funds available under Project BioShield, recognizing that significant efforts both upstream and downstream of the acquisition will be required to ensure the successful development, maintenance and utilization of these critical response assets, that may be needed in the event of a public health emergency.

The *HHS PHEMCE Implementation Plan for CBRN Threats* excludes pandemic influenza, which is addressed in the *HHS Pandemic Influenza Plan.* The *HHS Pandemic Influenza Plan* includes an overview of the threat of pandemic influenza, a description of the relationship of the *HHS Pandemic Influenza Plan* to other Federal plans, and an outline of key roles and responsibilities during a pandemic. It is aligned with the *National Strategy for Pandemic Influenza*, issued by President George W. Bush on November 1, 2005, and the *Implementation Plan for the National Strategy for Pandemic Influenza*, which guides the Nation's preparedness and response to an influenza pandemic. Significant progress has been made in the development and acquisition of medical countermeasures for pandemic influenza. Additional detailed information is available at *http://www.pandemicflu.gov.*

Current State of Medical Countermeasure Preparedness

To date, HHS has significantly expanded national medical countermeasure preparedness utilizing significant investments from throughout the HHS PHEMCE, including NIH research and development; CDC Division of the Strategic National Stockpile (DSNS) acquisition, storage, and maintenance of medical countermeasures; and substantive technical and regulatory support provided by FDA to product developers. Funding support by the NIH for basic research, product development, and clinical research of CBRN medical countermeasures has increased dramatically between Fiscal Year 2001 (FY 2001) to FY 2006. Funding for the DSNS has increased more than ten-fold in that same period, providing for the acquisition and stockpiling of medical countermeasures and supplies to protect the American public. Furthermore, the Project BioShield Act of 2004 (Pub. L. 108–276)[4] (Project BioShield) was enacted to accelerate the acquisition and availability of safe and effective medical countermeasures to protect the United States from CBRN threats. Project BioShield created a $5.6 billion Special Reserve Fund (SRF) for use over 10 years (FY 2004–FY 2013) to acquire appropriate medical countermeasures for DSNS.

During its first two years of implementation, Project BioShield acquisitions were guided by requirements derived from interagency deliberations in 2003 that involved Cabinet-level Departments and the Executive Office of the President. Under this initial strategy, HHS pursued acquisitions for those highest priority threats for which there were candidate products at relatively advanced stages of development and for which there were opportunities to have a significant impact on improving preparedness. These products included medical countermeasures for anthrax, smallpox, botulinum toxins, and radiological/nuclear agents—the four threat agents initially determined by DHS to pose a material threat to national security.[5] Acquisitions under Project BioShield to date include the currently licensed anthrax vaccine, anthrax therapeutics (monoclonal and human immune globulin), a pediatric formulation of potassium iodide to protect against absorption of radioactive iodine, calcium and zinc diethylenetriaminepentaacetate (DTPA), chelating agents to treat ingestion of certain radiological particles, and botulinum antitoxin.

Additional acquisitions of medical countermeasures for the DSNS have also provided a substantial preparedness level for a number of material threats. Specifically, DSNS inventory includes smallpox vaccine to immunize every American and Vaccinia Immune Globulin to treat complications that may arise from smallpox vaccination; anthrax therapeutics and a substantial level of antibiotics to provide treatment (thousands of doses) or prophylaxis (millions of doses) for bacterial threat agents anthrax, plague and tularemia; thousands of treatment courses of the chelating agent Prussian Blue (which mitigates internal absorption of cesium-137, a component of dirty bombs); enough potassium iodide tablets (which protects against radioactive iodine) for over one million people; thousands of courses of growth factors that could be useful for addressing the hematopoietic effects of acute radiation syndrome (ARS); CHEMPACKs (pre-positioned antidotes for volatile nerve agent exposure) distributed throughout the country; and general supplies that will be required to treat the complex array of medical problems following a nuclear attack, including antibiotics, anti-nausea drugs, and large quantities of supplies to treat burn and blast injuries. Some of these stockpiled products are licensed, approved, or cleared by FDA for use as medical countermeasures. Others are investigational and would need to be used under an Investigational New Drug application or an Emergency Use Authorization[6]. In 2002, DSNS began participating in the Shelf Life Extension Program (SLEP) with FDA. SLEP allows

[1] *www.whitehouse.gov/news/releases/2002/12/WMDStrategy.pdf.*

[2] *www.whitehouse.gov/homeland/20040430.html.*

[3] *www.whitehouse.gov/news/releases/2007/02/20070207–2.html.*

[4] *http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ276.108.pdf.*

[5] The Project BioShield Annual Report to Congress July 2004–July 2006 is available at *http://www.hhs.gov/aspr/ophemc/bioshield/bioshieldreport/index.html*

[6] See *http://www.FDA.gov* for further information regarding the Investigational New Drug application and the Emergency Use Authorization

the extension of the expiration date of certain drugs in DSNS where adequate supporting data exist, so that critical medical countermeasures that are still safe and effective can continue to be used.

HHS has also acted to improve and strengthen the underlying national response capacity and distribution efficiency that is required to take full advantage of these stockpiled medical countermeasures. HHS has specifically worked to prepare public health systems for bioterrorism and other mass casualty incidents; expand America's public health laboratory capacity, a crucial element in detecting and understanding any disease outbreak; expand and improve communications capacity within the public health structure to make public communications clearer and faster in an emergency; enhance food defense and safety activities at the FDA; expand the biodefense research program at NIH; and address response capacity for at-risk populations including children, pregnant women, senior citizens and other individuals who have special needs in the event of a public health emergency, as determined by the Secretary.[7]

Development of the HHS PHEMCE Implementation Plan For Chemical, Biological, Radiological and Nuclear Threats

HHS approached the development of the *HHS PHEMCE Implementation Plan* recognizing that the past investments outlined above have resulted in an armamentarium of medical countermeasures in DSNS that provides a substantial preparedness level for a number of CBRN threats. HHS recognizes that while it was important to achieve the current level of preparedness, it is equally as important to maintain and improve this capability.

HHS PHEMCE has taken a holistic, end-to-end approach that considers multiple aspects of the medical countermeasures mission including research, development, acquisition, storage, maintenance, deployment, and guidance for utilization. Phase One of this approach established the *HHS Public Health Emergency Medical Countermeasures Enterprise Strategy for Chemical Biological, Radiological and Nuclear Threats (HHS PHEMCE Strategy*).[8] The September 2006 BioShield Stakeholders Workshop brought together stakeholders from all aspects of the mission to discuss the framework and approach for the *HHS PHEMCE Strategy.* The valuable input solicited from stakeholders at the Workshop, combined with the responses received to the medical countermeasures Request for Information issued in October 2006[9] and through the **Federal Register**, was incorporated into the *HHS PHEMCE Strategy.*

The HHS PHEMCE Strategy, published in the **Federal Register** on March 20, 2007, described a framework of strategic policy goals and objectives for identifying medical countermeasure requirements and establishing priorities for medical countermeasure evaluation, development and acquisition. These strategic policy goals and objectives were used to establish the Four Pillars upon which this *HHS PHEMCE Implementation Plan* is based.

Pillar One: Identify and Assess CBRN Threats

DHS leads the Federal response to National Response Plan incidents, conducts integrated assessments of the risks posed by CBRN agents, and issues Material Threat Determinations (MTDs) as to which CBRN pose a material threat sufficient to affect U.S. national security.[10] The Secretary of Homeland Security has issued MTDs for threat agents (Table 1) and has conducted Population Threat Assessments (PTA) to estimate the number of individuals who might be exposed to each of these threats in plausible, high-consequence scenarios. A Population Threat Assessment has been conducted for volatile nerve agents.

In the future, additional MTDs may be issued if technology advances or if our understanding of the potential threats changes. The PHEMCE strategy is to have specific medical countermeasures that address each of the threats for which an MTD has been issued while also providing broad spectrum medical countermeasures to address as many as is practicable of those threats that did not rise to the level of an MTD.

Table 1. Material Threat Determinations (MTDs) and Population Threat Assessment (PTAs) issued to date by the Department of Homeland Security

Bacillus anthracis (ANTHRAX)	Marburg virus (HEMORRHAGIC FEVER)
Botulinum toxins (BOTULISM)	Multi-drug resistant *Bacillus anthracis* (MDR ANTHRAX)
Burkholderia mallei (GLANDERS)	Radiological/Nuclear agents
Burkholderia pseudomallei (MELIODOSIS)	*Rickettsia prowazekii* (TYPHUS)
Ebola virus (HEMORRHAGIC FEVER)	Variola virus (SMALLPOX)
Franciscella tularensis (TULAREMIA)	Volatile nerve agents [PTA only]
Junin virus (HEMORRHAGIC FEVER)	*Yersinia pestis* (PLAGUE)

Pillar Two: Assess Medical/Public Health Consequences

The information supporting the MTDs and PTAs regarding population exposures from high consequence scenarios provided by DHS is used by HHS to inform subsequent medical and public health consequence assessments using multiple sources of information, including modeling. HHS uses modeling to help to explore potential outcomes when medical countermeasures are employed in operationally realistic timelines. The HHS assessments provide public health impact estimates for a given threat scenario and use of medical countermeasures for each threat agent.

[7] As defined in the Pandemic and All-Hazards Preparedness Act (P.L.109–417), which is available at *http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ417.109.pdf.*

[8] Available at *http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2007_register&docid=%5bDOCID:fr20mr07–65.*

[9] *http://www.fbo.gov/servlet/Docments/R/589030.*

[10] Material Threat Determinations are authorized under section 319 F–2(c)(2) of the Public Health Service Act, as added by section 3 of the Project BioShield Act and are a legally required precursor to procurements under that authority.

Pillar Three: Establish Medical Countermeasure Requirements That Incorporate Assessments of Current Levels of Preparedness, Concepts of Utilization, and Product Specifications

Our current state of preparedness and medical countermeasure requirements have been assessed for these fourteen CBRN threats. To establish medical countermeasure requirements for the top priority threat agents, HHS combines the threat prioritization and medical and public health consequence assessments, along with subject matter expert evaluations, domestic and international intelligence information, and information on current State, local and tribal response capabilities.

Pillar Four: Identify and Prioritize Near-, Mid-, and Long-Term Development and Acquisition Programs, Informed by Assessment of the Maturity of the Product Development Pipeline and Estimated Costs

The mission to develop and acquire agent-specific medical countermeasures for the entire U.S. population for all fourteen threats and broad spectrum medical countermeasures against the remaining current and future threats encompasses a vast range of activities and dictates priority-setting. The process for setting the priorities for the portfolio of investments ultimately outlined in this plan required careful consideration and deliberation. Specifically, HHS PHEMCE evaluated three possible approaches during the priority setting process. The first option was to focus only on a single, highest priority threat. In line with this, all available acquisition dollars would be spent trying to fully address the requirements for this one agent with the aim of eliminating it as a material threat to national security. The second option was to divide the available resources equally among the known fourteen threats. The third option, and the approach that the PHEMCE ultimately pursued, was to prioritize strategic policy decisions, framed by the *HHS PHEMCE Strategy*, which will most effectively improve overall public health preparedness. This decision-making process to set priorities included extensive discussion with Federal government subject matter experts [11] and was guided by the principles of the National Strategy for *Medical Countermeasures against Weapons of Mass Destruction.* As a result, HHS has prioritized the medical countermeasures programs—including, research, development, and acquisition in the near-term, mid-term and long-term—that were determined to provide the greatest opportunities to improve public health emergency preparedness across the threat spectrum.

The key elements that established the foundation for the priority-setting decisions were as follows:

Prevention Versus Mitigation and Treatment

HHS has generally adopted a strategy of developing and acquiring medical countermeasures for post-event response to CBRN threats. Preventive measures are appropriate only for threats of such potential catastrophic consequence that a pre-event strategy will be examined in order to reduce vulnerability and mitigate post-event consequences. Therapeutics and diagnostics or the use of post-event prophylaxis will be the preferred strategy for all other threats. Priority will be placed on medical countermeasures that focus on post-event prophylaxis or post-exposure treatment.

Concept of Operations

In alignment with the National Strategy for *Medical Countermeasures against Weapons of Mass Destruction*, HHS will prioritize the development and acquisition of medical countermeasures that are associated with an effective concept of operations (CONOPs). These CONOPs include a deployment strategy and utilization policy that is supportable by the present and future programmed distribution capabilities of Federal, State, local, and tribal public health emergency responders to rapidly ship and distribute critical items following a CBRN event. Within HHS, ASPR coordinates with the CDC Coordinating Office for Terrorism Preparedness and Emergency Response (COPTER) in determining processes, procedures, tactics, and techniques for how DSNS deploys countermeasures [12] and the utilization strategies for those materials and medical countermeasures. ASPR's Office of Preparedness and Emergency Operations (OPEO) works with its response partners, using event and response modeling, to outline how the current DSNS inventory will be used. These approaches are exercised with interagency partners to ensure that the plans are based on realistic and achievable timelines.

[11] Including subject matter experts from HHS (CDC, FDA, and NIH), DOD, DHS, VA, and the respective HHS PHEMCE Chemical, Biologics, Radiological and Nuclear Working Groups.

[12] The authority of the Secretary of HHS to deploy the SNS is codified at 42 U.S.C. § 247d–6b.

The CONOPs for a particular threat scenario and medical countermeasure are a crucial component in setting specific product requirements and contribute directly to the acquisition strategy. While there is much in common in medical countermeasure development for civilian and military medical countermeasures, CONOPs for HHS and DOD, respectively, have differences which must be considered in the requirements and acquisitions processes. HHS is committed to continuing to work with all its emergency responder partners to improve public health response capabilities.

Broad Spectrum Medical Countermeasures and Platform Technologies

A fixed defense [13] or ''one-bug, one-drug'' approach for medical countermeasure development is determined to be effective and viable for some of the highest priority threats such as smallpox and anthrax. As the list of material threats increases, and technology advances, HHS will be focusing its medical countermeasure research, development and acquisition efforts on broad spectrum and platform approaches.

Preparing for New Threats

In order to address emerging, enhanced, and advanced threats,[14] HHS will be investing in research and development on innovative approaches and platform technologies.[15] These technologies will facilitate rapid identification and characterization of novel threat agents, thereby creating the capability to rapidly produce relevant medical countermeasures. This policy is aligned with the National Strategy for *Medical Countermeasures against Weapons of Mass Destruction* which targets the use of existing, proven approaches for developing medical countermeasures to address challenges posed by traditional CBRN agents while calling for a flexible capability to develop new medical countermeasures. These latter activities emphasize the need to capitalize upon the development of innovative and future technologies that will enhance our ability to respond swiftly and effectively to potential, emerging, and future unknown CBRN threats. This will require targeted, balanced, and sustained investments to support fundamental basic research to discover new technologies and update platforms as well as applied research for technology development to deliver new medical capabilities and countermeasures.

Top Priority Medical Countermeasure Research, Development, and Acquisition Programs to Increase Public Health Emergency Preparedness

Following the principles and processes described above, HHS has assessed the top priority CBRN threats from a medical countermeasure perspective and has developed medical countermeasure acquisition priorities for the near-term (FY 2007–FY 2008), the mid-term (FY 2009–FY 2013), and, in less detail, the long-term (beyond FY 2013).[16] This prioritization spans the CBRN threat spectrum and best utilizes available resources in addressing the highest priority threats to maximize risk mitigation. Table 2 arrays the top priority medical countermeasure programs against the specific threat agents addressed by the program. The broad spectrum antibiotic, broad spectrum antiviral, and diagnostics programs address multiple threat agents, while other programs are, of necessity, agent-specific.

Medical countermeasure requirements are based primarily on the number of persons exposed to clinically significant levels of a threat agent in a single-event, plausible, high-consequence scenario. In setting appropriate targets for an acquisition program, a number of factors in addition to the single event, exposure-based medical countermeasure requirement could be considered, including:

- Multiple events
- Citizens concerned about exposure [17]
- The lack of availability of rapid, point-of-care diagnostics
- Potential nationwide demand after a single large-scale event
- Pre-positioning of individual medical countermeasures to meet specific response time requirements
- Economies of scale for production [18]
- Providing a target acquisition size sufficient to drive industrial development of the medical countermeasure.

HHS will continue to coordinate medical countermeasure development and acquisition efforts with DOD; however, separate development and acquisition programs may be necessary in situations where military requirements differ from civilian requirements, including with regard to concepts of use of particular countermeasures. Consistent with the National Strategy for *Medical Countermeasures against Weapons of Mass Destruction*, the Secretary of Health and Human Services is tasked with civilian medical countermeasure preparedness, and it is National policy that ''the Secretary of Defense shall retain the exclusive responsibility for research, development and acquisition of medical countermeasures to prevent or mitigate the health effects of WMD threats * * * to the Armed Forces.'' [19]

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[13] Relman DA. Bioterrorism—Preparing to Fight the Next War, NEJM, 2006, 354(2):113–115. In the context of defense against biological threats, a fixed defense is a medical countermeasure intended for use against a specific organism and not useful in scenarios that employ a different organism.

[14] As defined in the National Strategy for *Medical Countermeasures against Weapons of Mass Destruction:* Enhanced Agents are traditional agents that have been modified or selected to enhance their ability to harm human populations or circumvent current countermeasures, such as a bacterium that has been modified to resist antibiotic treatment; Emerging Agents are previously unrecognized pathogens that might be naturally occurring and present a serious risk to human populations, such as the virus responsible for Severe Acute Respiratory Syndrome (SARS); and Advanced Agents are novel pathogens or other materials of biological nature that have been artificially engineered in the laboratory to bypass traditional countermeasures or produce a more severe or otherwise enhanced spectrum of disease.

[15] Examples of platform technologies include strategies that permit rapid commercial scale production of threat-specific countermeasures or expression systems that permit rapid production of new vaccines.

[16] SRF that supports Project BioShield released $3.4 billion for use between FY 2004–2008 and the remaining $2.2 billion will be available for use between FY 2009–2013.

[17] Non-exposed population seeking medical care for non-specific symptoms or concerns about exposure.

[18] A production process in which an increase in the number of units produced causes a decrease in the average cost of each unit.

[19] *www.whitehouse.gov/ news/releases/2007/ 02/ 20070207-2.html.*

Table 2. CBRN Threats and Projected Future Top Priority Medical Countermeasure Programs

TOP PRIORITY CBRN THREATS (LISTED ALPHABETICALLY)	PROJECTED FUTURE TOP PRIORITY MEDICAL COUNTERMEASURE (MCM) PROGRAMS												
	Anthrax antitoxin(s)	Anthrax vaccine	ARS/DEARE MCM(s)	Biodosimetry, Bioassay	Broad spectrum antibiotic(s)	Broad spectrum antiviral(s)	Diagnostics	Enterprise CHEMPACKs	Filovirus MCM(s)	Radionuclide-specific agent(s)	Smallpox antiviral(s)	Smallpox vaccine	Volatile nerve agent single antidote
Bacillus anthracis ANTHRAX / Multi-drug resistant *Bacillus anthracis* MDR ANTHRAX	✦	✦			✦		✦						
Botulinum toxins BOTULISM							✦						
Burkholderia mallei GLANDERS / *Burkholderia pseudomallei* MELIOIDOSIS					✦		✦						
Filoviruses (Ebola and Marburg) HEMORRHAGIC FEVER						✦	✦		✦				
Francisella tularensis TULAREMIA					✦		✦						
Junin virus ARGENTINE HEMORRHAGIC FEVER						✦	✦						
Radiological/nuclear agents			✦	✦						✦			
Rickettsia prowazekii TYPHUS					✦		✦						
Variola virus SMALLPOX						✦	✦				✦	✦	
Volatile nerve agents								✦					✦
Yersinia pestis PLAGUE					✦		✦						

Strategies for Addressing High Priority Medical Countermeasures

Research and Development

NIH is the lead agency within the Federal Government for conducting and supporting biomedical research relating to causes, diagnosis, treatment, control, and prevention of diseases. NIH will align research and development efforts with the PHEMCE priority medical countermeasure programs. In addition, NIH will support Research and Development for next-generation products to replace currently-held medical countermeasures in DSNS, as needed. These next generation products include medical countermeasures with broad spectrum activity against a wide variety of threat agents; broad spectrum technologies that enhance effectiveness of multiple classes of medical countermeasures; and broad spectrum platforms that permit more rapid generation of required medical countermeasures. Continued research and development efforts will ensure a sustainable, continuous stream of promising medical countermeasures in the pipeline that are aligned with top priority HHS PHEMCE requirements for future acquisitions and/or replacement of DSNS inventory. NIH's long-term focus is on platform technologies and broad spectrum medical countermeasures that will allow for the rapid introduction of additional response capabilities for emerging infectious agents.

Advanced Development [20]

The use of advanced development efforts that support multiple candidates for each medical countermeasure need is a key element to mitigating risk in the Project BioShield acquisition phase of the product development pathway. The Pandemic and All-Hazards Preparedness Act (Pub. L. 109–417) established the Biomedical Advanced Research and Development Authority (BARDA). Utilizing those tools, HHS plans to promote innovation, reduce risk to both medical countermeasure developers and the Government, and invest in medical countermeasure advanced development that will carry products through the crucial middle phase [21] of drug development between basic research and acquisition of final products. HHS anticipates that available funding through these authorities, in FY 2007 and beyond, will be aligned with the highest priority medical countermeasure development programs. Finally, Advanced Development activities will depend on congressional approval of the President's FY 2008 budget request of $189 million. The future funding levels for BARDA remain to be determined.

Projected Acquisitions

The HHS PHEMCE will consider opportunities for acquiring medical countermeasures using both DSNS appropriations as well as SRF monies under Project BioShield. Acquisitions under DSNS will be limited to commercially available products. Current funding levels were considered in projecting acquisition forecasts. While BARDA funding has been established to support the advanced development of medical countermeasures, Project BioShield acquisition contracts may still include late-stage development costs for scale-up manufacturing, clinical trials, and pivotal animal efficacy studies, in addition to final production and delivery.

The near-term is defined as FY 2007–FY 2008, which is the time frame of allocation of approximately half of the Project BioShield SRF. The mid-term is defined as FY 2009–FY 2013, which is the remainder of the ten year duration of the Special Reserve Fund. Medical countermeasures will be procured in the near-term and mid-term using both the SRF as well as from the DSNS appropriations. During the near-term, HHS also will pursue acquiring a number of medical countermeasures for which utilization of the Project BioShield Special Reserve Fund has been approved, but for which funds have not yet been fully obligated.

Table 3 summarizes the proposed near-term and mid-term acquisitions for the priority medical countermeasures. In some cases, the estimated funding ranges indicated are based on identified potential medical countermeasure candidates currently under development; whereas in other cases the estimated ranges are based on industry standard information for vaccine and drug development costs. Descriptions of the acquisitions for priority medical countermeasures follow Table 3.

[20] The Pandemic and All-Hazards Preparedness Act (Pub. L. 109–417) definition of advanced research and development: ''with respect to a product that is or may become a qualified countermeasure or a qualified pandemic or epidemic product, activities that predominantly are conducted after basic research and preclinical development of the product; and are related to manufacturing the product on a commercial scale and in a form that satisfies the regulatory requirements under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act.''

[21] Often referred to as the ''Valley of Death.''

Table 3. Proposed Near-Term and Mid-Term Acquisitions for High Priority Medical Countermeasures to Address CBRN Threat Agents

BIOLOGICAL THREATS	Near-Term (FY 2007-08)		Mid-Term (FY 2009-13)	
	Funding Source	Funding Level[1]	Funding Source	Funding Level[1, 2]
Diagnostics			SRF	X
Broad spectrum antibiotic(s)	DSNS	X	DSNS, SRF	X, XX
Anthrax antitoxin(s)			SRF	XX
Anthrax vaccine(s)	SRF	XX		
Medical Countermeasure(s) for Filoviruses			SRF	XX
Smallpox antiviral(s)			SRF	X
Smallpox vaccine	SRF	XX		
RADIOLOGICAL and NUCLEAR THREATS	**Near-Term (FY 2007-08)**		**Mid-Term (FY 2009-13)**	
	Funding Source	Funding Level[1]	Funding Source	Funding Level[1,2]
Medical Countermeasure(s) for ARS/DEARE	SRF	XX	SRF	XX
Biodosimetry, Bioassay			SRF‡	X
Radionuclide-specific agent(s)			SRF	X
CHEMICAL THREATS	**Near-Term (FY 2007-08)**		**Mid-Term (FY 2009-13)**	
	Funding Source	Funding Level[1]	Funding Source	Funding Level[1,2]
Enterprise CHEMPACKs			DSNS	XX

KEY

DSNS Anticipated to be funded through the CDC Division of the Strategic National Stockpile budget, pending availability of funds.

SRF Anticipated Project BioShield Special Reserve Fund acquisition with remaining available funds.

SRF‡ While the diagnostics portion of this requirement may be funded through the Project BioShield Special Reserve Fund, appropriate funding to establish the network of biodosimetry and radionuclide bioassay laboratories is yet to be determined.

X Currently estimated to be less than or equal to $100 million[3]

XX Currently estimated to be greater than $100 million[3]

[1] Funding is cumulative within the time period indicated.

[2] Uncertainties in funding support throughout the pipeline in the mid-term preclude making more definitive projections.

[3] These estimates are not final. Funding levels are subject to change.

PROJECTED NEAR-TERM (FY 2007–FY 2008)

Medical Countermeasure Development and Acquisition Programs To Enhance Preparedness

Programs for Biological Threats

Broad Spectrum Antibiotic(s)

MTD: *Bacillus anthracis and multi-drug resistant bacillus anthracis, burkholderia mallei, burkholderia pseudomallei, franciscella tularensis, rickettsia prowazekii, yersinia pestis.*

Many of MTDs address bacterial species that can be treated using antibiotics. Broad spectrum antibiotics, therefore, will continue to be a critical component of strategy HHS will take to maintain and improve public health preparedness. For each biological threat agent or class of agents, however, there is a limited array of antibiotics with demonstrated efficacy. In the near-term, HHS will continually evaluate the antibiotics in the DSNS and, as needed, will acquire commercially available antibiotics using DSNS appropriations.

Anthrax Vaccine(s)

MTD: *Bacillus anthracis, multi-drug resistant bacillus anthracis.*

Antibiotics represent the first line of defense to protect the nation following an anthrax attack. However, anthrax vaccines are also an essential element of our national preparedness. Vaccines may be given as post-exposure prophylaxis in combination with antibiotics to potentially provide longer-term protection; this combination may also allow for a reduction in the duration of the antibiotic regimen. Vaccines can also provide pre-event protection to the relatively small population that is at high risk of frequent occupational exposure to *Bacillus anthracis.*

In December 2006, a contract for the development and acquisition of a recombinant Protective Antigen (rPA) anthrax vaccine was terminated by HHS; however, the Department remains committed to acquiring next-generation anthrax vaccines that will be part of a balanced and diversified portfolio of medical countermeasures. HHS has developed a comprehensive strategy for advanced development and acquisition of current and next generation anthrax vaccines and anticipates that these activities will be pursued in the near-term.

Smallpox Vaccine(s)

MTD: *Variola virus.*

HHS has made significant progress in providing smallpox vaccine to the DSNS. In addition, a requirement has been established for a smallpox vaccine to protect immunocompromised persons for whom use of the existing smallpox vaccines is medically contraindicated in the absence of smallpox exposure.

One candidate next-generation smallpox vaccine, modified vaccinia Ankara (MVA), is based on a strain of the vaccinia virus that, in contrast to current smallpox vaccines such as Dryvax, does not replicate effectively in human cells and, therefore, may cause fewer side effects. The MVA development programs were supported by the National Institute of Allergy and Infectious Diseases (NIAID) with milestone-driven contract awards in 2003 and 2004. HHS is well-advanced in the pre-award stage of an MVA vaccine acquisition program.

Programs for Radiological and Nuclear Threats

ARS/Hematopoietic Syndrome Medical Countermeasure(s)

MTD: *Radiological/nuclear agents.*

HHS regards radiological and nuclear agents as a significant threat to national security and is committed to purchasing safe and efficacious medical countermeasures to treat Acute Radiation Syndrome (ARS). In March 2007, HHS withdrew the ARS RFP because it was determined, after extensive scientific and technical expert evaluation, that no competing offeror had a product that met USG requirements for a Project BioShield acquisition. HHS will continue to pursue an initial acquisition of a safe and effective medical countermeasure to treat ARS. In moving forward to meet this goal, HHS will make use of scientific developments that have occurred since the previous RFP closed, as well as new authorities provided by the Pandemic and All-Hazards Preparedness Act that could accelerate the advanced development of promising countermeasures.

HHS supports further development of the radiological and nuclear medical countermeasure pipeline. The NIAID's Radiation Countermeasures Research Program has funded numerous projects, including: ARS medical countermeasure screening programs in cell-based and rodent models at multiple institutions around the country; development of three Good Laboratory Practices (GLP) animal testing facilities to evaluate the efficacy of medical countermeasures against ARS; eight Centers for Medical Countermeasures against Radiation at academic institutions around the country; and intramural research programs at the DOD Armed Forces Radiobiology Research Institute (AFRRI) and the National Cancer Institute.

PROJECTED MID-TERM (FY 2009–FY 2013)

Medical Countermeasure Development and Acquisition Programs To Enhance Preparedness

HHS will pursue the following medical countermeasure acquisitions in the mid-term using the remaining SRF and pending availability of other funding for those acquisitions that do not use the SRF. These anticipated acquisitions are also predicated on the availability of products at the appropriate developmental stage that meet U.S. Government civilian requirements.

Programs for Biological Threats

The ideal medical countermeasures for biological agents will be highly effective for post-exposure prophylaxis as well as early symptomatic treatment, will display an excellent safety profile and could be easily self-administered.

Broad Spectrum Antibiotic(s)

MTD: *Bacillus anthracis, multi-drug resistant bacillus anthracis. burkholderia mallei, burkholderia pseudomallei, francisella tularensis, rickettsia prowazekii, yersinia pestis.*

In addition to the near-term strategy for acquisition of commercially available antibiotics, HHS anticipates maintaining a robust basic research and development program along with advanced development for broad spectrum antimicrobials that will specifically provide support for regulatory approval for clinical indications that address bacterial agent MTDs. In order to better balance antimicrobial DSNS holdings in light of newer MTDs, HHS will pursue a potential acquisition of additional broad spectrum antimicrobials in the mid-term.

Diagnostics (Point-of-Care)

MTD: *All biological threat agents.*

Following a terrorist event, clinical diagnostic assays (*in vitro* diagnostics, IVDs) are critical tools for distinguishing infected (symptomatic) individuals needing treatment from potentially exposed but asymptomatic individuals needing post-exposure prophylaxis. Overall, the requirements for diagnostic assays to facilitate a response to a bioterrorism event will focus on rapid, point-of-care assays. Rapid triaging of the symptomatic patients will be required to provide, as necessary, treatment, isolation and implementation of universal precautions for infectious diseases and may also be useful in the

allocation of limited critical therapeutic materials to only those patients in need. Multiplexed, adaptive platforms that confer flexibility, offer alternative commercial opportunities, and allow for the rapid introduction of additional tests for emerging infectious agents are highly desired.

These IVDs used for clinical purposes are distinguished from detection assays used for environmental samples (air, water, food, surface swabs) in that they are required to be approved or cleared by the FDA. To date, limited incentives have been available to sustain commercial market production of IVDs; however, once specific requirements in this area are developed and prioritized, HHS will pursue a potential mid-term acquisition of biological agent diagnostics to enhance public health preparedness capability.

Anthrax Antitoxin

MTD: *Bacillus anthracis, multi-drug resistant bacillus anthracis.*

The primary mortality and morbidity of anthrax disease is mediated through toxins produced by the bacteria, B. *anthracis.* Antibiotics (currently within DSNS) target the B. *anthracis* bacteria itself; while vaccines (discussed under Near-Term Acquisitions) provide long-term protection from disease. Antitoxins are required to neutralize the effects of the toxins and may contribute to a more successful therapeutic outcome. Given the current status of anthrax antitoxins and animal model development, HHS will continue its phased acquisition program and will pursue a mid-term acquisition of additional anthrax antitoxin to allow HHS to more fully meet medical countermeasure requirements, including to address the threat from MDR anthrax.

Filovirus Medical Countermeasure(s)

MTD: *Ebola virus, marburg virus.*

Infection with filoviruses produces an aggressive disease that is highly lethal. Currently, no FDA-approved filovirus-specific medical countermeasures exist. An antiviral is preferred to treat infected patients and to provide pre-exposure prophylaxis to health care workers and personal contacts. A vaccine will be useful for civilian populations if it provides rapid onset of protective immunity. HHS will continue to invest in research and development and will pursue an acquisition for filovirus medical countermeasures in the mid-term.

Smallpox Antiviral

MTD: *Variola virus.*

Currently there is no treatment available for smallpox disease once the symptoms manifest. An effective antiviral treatment could mitigate the effects of smallpox disease. It is likely that such an antiviral may also be effective against other pox viruses. Given the current status of the most advanced products as well as the status of animal model development, HHS will pursue a mid-term acquisition of a smallpox antiviral for the treatment of smallpox. The ideal antiviral will be highly effective post-exposure as well as an effective treatment early in the symptomatic phase of the disease.

Programs for Radiological and Nuclear Threats

ARS/DEARE Medical Countermeasure(s)

MTD: *Radiological/nuclear agents.*

Acute Radiation Syndrome (ARS) often called radiation sickness, results when humans are exposed to a large dose of ionizing radiation. ARS develops in the timeframe of hours to weeks, and the Delayed Effects of Acute Radiation Exposure (DEARE) injury in weeks to months following radiation exposure. HHS will pursue one or more ARS/DEARE medical countermeasure acquisition(s) in the mid-term to continue the phased acquisition strategy launched in the near-term.

Biodosimetry and Bioassay

MTD: *Radiological/nuclear agents.*

Biodosimetry and radionuclide bioassay capabilities are essential for medical management of ARS/DEARE following acute radiation exposure and are integral to triage and management processes. HHS anticipates that rapid biodosimetry assays for on-scene triage should be available for acquisition in the mid-term. A system of biodosimetry and radionuclide bioassay laboratories is also proposed to increase overall national capacity. While the diagnostics portion of this requirement may be funded through the Project BioShield SRF, appropriate funding to establish this laboratory network is yet to be determined.

Radionuclide-Specific Medical Countermeasure(s)

MTD: *Radiological/nuclear agents.*

Radionuclide-specific medical countermeasures are a key component to managing the medical consequences of radiation dispersal device (RDD) events, both explosive and non-explosive, as well as nuclear power plant events. In the near term, HHS will continue to fund the development of improved formulations of diethylenetriaminepentaacetate (DTPA) and other novel decorporating agents that remove radioactive particles from the body. If continued progress is made on the radionuclide-specific countermeasures currently under development, it is conceivable that oral formulations of DTPA (which would considerably ease the logistical requirements for rapid delivery of this medical countermeasure) and/or other novel decorporating agents could be available for acquisition in the mid-term.

Programs for Chemical Threats

Enterprise CHEMPACKs

PTA: *Volatile nerve agents.*

The CHEMPACK program is an ongoing initiative of the DSNS, begun in 2003, that provides antidotes (three countermeasures used concomitantly) to volatile nerve agents for pre-positioning by State, local, and/or tribal officials throughout the U.S. In its current form, the program will receive continued funding in the near-term for procurement and fielding of additional CHEMPACKs, replacement of expired product, and administrative support. The proposed Enterprise CHEMPACK program would build upon the existing system, improving it by adding an education, training and exercise component and by optimizing the pre-positioning of antidotes. In the near-term, HHS will begin performing the operations analysis that is prerequisite to such improvements. It is anticipated that acquisition of some next-generation replacement products and the implementation of changes to improve the program could occur in the mid-term, pending availability of DSNS funds.

PROJECTED LONG-TERM (BEYOND FY 2013)

Medical Countermeasure Development and Acquisition Programs To Enhance Preparedness

Program for Biological Threats

Broad Spectrum Antiviral(s)

MTD: *Ebola Virus, Junin Virus, Marburg Virus, Variola Virus.*

Three families of viruses are represented among the existing MTDs: *Poxviridae* (variola virus), *Filoviridae* (Ebola and Marburg viruses), and *Arenaviridae* (Junin virus). These different viral families have diverse biological and pathological characteristics and cause unique diseases in humans. All of these viruses can be disseminated via aerosolization, a feature which enhances their potential use as bioterrorism agents. There are no approved antiviral drugs available for either post-exposure prophylaxis or for

therapeutic use for any of these viral diseases. Overall, the development of broad spectrum medical countermeasures that can address several threat agents would maximize the efficiency and flexibility of the DSNS, thereby reducing storage and maintenance costs. HHS will prioritize research and development funding in this area in the near- and mid-terms. Due to its relative immaturity in the development pipeline, it is unlikely that a broad spectrum antiviral will be acquisition-ready until after FY 2013.

Program for Chemical Threats

Volatile Nerve Agent Single Antidote

PTA: *Volatile Nerve Agents.*

The optimal medical defense against volatile nerve agents would be a single, rapidly effective countermeasure that could be used, for example, via intranasal or inhaled routes and by untrained persons at risk or by first responders dealing with large numbers of exposed individuals. HHS will continue research and development funding in this area in the near- and mid-terms. Given the current immature status of the development pipeline, a single antidote for volatile nerve agents would likely not be available for acquisition until the long-term timeframe.

Conclusion

This *HHS PHEMCE Implementation Plan* identifies top priorities for medical countermeasure research, development and acquisition programs that HHS has determined, in collaboration with interagency partners, to have the greatest potential to improve public health emergency preparedness. It is anticipated that this plan will be reviewed at least biennially to encompass potential changes in assessments of the threat, consequences (particularly with regard to the evolution of CONOPs), and maturity of the medical countermeasure development pipeline.

The prioritization of medical countermeasure programs described in this *HHS PHEMCE Implementation Plan* represents the current thinking of HHS informed by material threat determinations, population threat assessments, or the assessments of medical and public health consequences. DHS is conducting an integrated CBRN threat assessment, to be completed in June 2008 that will further inform the next version of the *HHS PHEMCE Implementation Plan.* Additionally, future versions are anticipated to incorporate more detailed assessments of potential multipliers of medical countermeasure requirements, based on the potential for enhanced, emerging, or advanced biological agents, multiple and simultaneous CBRN events and other factors informed by scientific and threat analysis. As State, local, and tribal medical countermeasure delivery capabilities and event response planning evolve, they will also open new flexibilities with respect to the types of medical countermeasures that can be incorporated into Federal planning efforts, and will influence HHS assessments of potential medical and public health consequences following CBRN events.

The development and acquisition strategies to most effectively improve preparedness resulted from critical evaluation of the status of medical countermeasure development pipelines. HHS recognizes that developing, acquiring, and utilizing medical countermeasures to prepare for and respond to CBRN events requires significant resources and unprecedented cooperation among many stakeholders, including Federal counterparts outside HHS; private industry (domestic and international); State, local and tribal governments; first responders and healthcare workers; academia; and the public. HHS will build upon its 2006 RFI for medical countermeasures against CBRN threats, including the technology readiness levels (TRLs) defined in that RFI, to continue to explore new, more efficient ways to reach out to the academic and medical countermeasure development communities to ensure that future versions of the *HHS PHEMCE Implementation Plan* are informed by the latest breakthroughs in the field.

In addition, while this *HHS PHEMCE Implementation Plan* focuses on the further enhancement of public health emergency preparedness, HHS is simultaneously evaluating the costs and benefits associated with the mid- and long-term maintenance of existing and projected stockpiles of medical countermeasures. HHS anticipates that such an evaluation will be detailed in a future version of the *HHS PHEMCE Implementation Plan.*

Finally, Advanced Development activities will depend upon congressional approval of the President's FY 2008 budget request and will increase the chance of programmatic success. Through the Pandemic and All-Hazards Preparedness Act, HHS now has the authority to promote innovation, increase the potential for success for both medical countermeasure developers and the Government, and invest in medical countermeasure advanced development that will carry products across the so-called ''Valley of Death'' to meet medical countermeasure requirements. It is anticipated that future versions of the *HHS PHEMCE Implementation Plan* will more fully incorporate implementation of these authorities and funding levels that may be appropriated in support of the robust advanced development programs that are critical to mission success.

The prioritization of medical countermeasures to improve public health preparedness reflected in *this HHS PHEMCE Implementation Plan* was an interagency process led by HHS and involving significant collaboration with DHS, DOD, VA, and others. The *HHS PHEMCE Implementation Plan* has also benefited tremendously from the information provided by Stakeholders, particularly at the BioShield Stakeholders Workshop held in September 2006, and from the many formal comments received in response to the **Federal Register** notice of the draft *HHS PHEMCE Strategy.* Notice of the issuance of this *HHS PHEMCE Implementation Plan* will be posted in the **Federal Register** and HHS welcomes comments from stakeholders.

The *HHS PHEMCE Implementation Plan* will be a feature of the upcoming HHS Public Health Emergency Medical Countermeasures Enterprise Stakeholders Workshop to be held in Washington, DC, July 31—August 2, 2007. HHS is committed to improving transparency and continuing to find the most appropriate venues to work with stakeholders who are likewise committed to meeting the goals of this critical mission of preparing the nation for the adverse health consequences of public health emergencies.

Improving preparedness will be an ongoing process as science advances, innovations mature, and the threat scope changes. HHS resources beyond the SRF, when it ends in FY 2013, will continue to be strategically invested in programs throughout the medical countermeasure development and acquisition pipeline to achieve this goal. It is anticipated that targets for the timeframe beyond FY 2013 will be articulated with increasing clarity and granularity with each successive revision of the *HHS PHEMCE Implementation Plan.*

Finally, to successfully execute the program objectives outlined in the *HHS PHEMCE Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats*, ASPR will strengthen and build upon its achievements to develop, recruit, and support a world-class workforce. To realize this goal, ASPR will intensify its efforts to attract

and expedite hiring of qualified candidates; focus and align training, education, and career development; recognize staff accomplishments; and foster learning and growth with improved knowledge management.

Dated: April 17, 2007.

Gerald Parker,

Principal Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services.

[FR Doc. 07–1983 Filed 4–18–07; 12:17 pm]

BILLING CODE 4150–37–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–07–0217]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Vital Statistics Training Application, OMB No. 0920–0217–Extension-National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In the United States, legal authority for the registration of vital events, *i.e.*, births, deaths, marriages, divorces, fetal deaths, and induced terminations of pregnancy, resides individually with the States (as well as cities in the case of New York City and Washington, DC) and Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. These governmental entities are the full legal proprietors of vital records and the information contained therein. As a result of this State authority, the collection of registration-based vital statistics at the national level, referred to as the U.S. National Vital Statistics System (NVSS), depends on a cooperative relationship between the States and the Federal government. This data collection, authorized by 42 U.S.C. 242k, has been carried out by NCHS since it was created in 1960.

NCHS assists in achieving the comparability needed for combining data from all States into national statistics, by conducting a training program for State and local vital statistics staff to assist in developing expertise in all aspects of vital registration and vital statistics. The training offered under this program includes courses for registration staff, statisticians, and coding specialists, all designed to bring about a high degree of uniformity and quality in the data provided by the States. This training program is authorized by 42 U.S.C. 242b, section 304(a). In order to offer the types of training that would be most useful to vital registration staff members, NCHS requests information from State and local vital registration officials about their projected needs for training. NCHS also asks individual candidates for training to submit an application form containing name, address, occupation, work experience, education, and previous training. These data enable NCHS to determine those individuals whose needs can best be met through the available training resources. NCHS is requesting 3 years of OMB clearance for this project. There is no cost to respondents in providing these data other than their time. The total estimated annualized burden hours are 44.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State, local, and Territory Registration Officials	57	1	20/60
Training applicants	100	1	15/60

Dated: April 17, 2007.

Maryam Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–7648 Filed 4–20–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–07–06AO]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Joan Karr, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Evaluation of an Occupational Safety and Health Program for the Small Business Wood Pallet Industry, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).