Supporting Statement for Request for Clearance:

MEDICALCOUNTERMEASURES.GOV: MEETING REQUEST ROUTING FUNCTIONALITY

OMB No. 0990-New

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Supporting Statement for MedicalCountermeasures.gov

Background

During the BioShield Stakeholders Workshop, HHS Secretary Michael O. Leavitt announced that HHS would develop a stakeholders' portal, which would be "a web-based system through which those in industry and the research and development community can reach the people they need in the federal government, whether they're looking at a basic level of research or focused on end-stage development." In fulfillment of Secretary Leavitt's vision, the Office of the Assistant Secretary for Preparedness and Response (ASPR), in consultation with its partners in the federal government, is developing MedicalCountermeasures.gov. Its mission is to facilitate communication between federal government agencies and public stakeholders to enhance the Nation's public health emergency preparedness. Our stakeholder groups are primarily members of industry and academia who are involved in the research and development of medical countermeasures to naturally occurring and intentional threats to public health.

MedicalCountermeasures.gov routes requests for meetings with the government from our stakeholders in industry and academia to the appropriate personnel in at the Department of Health and Human Services (HHS). The process is completely voluntary, but HHS encourages frequent and open communication between the HHS and its stakeholders in industry and academia. In order for the government to help its stakeholders find the most appropriate human resources in the federal government, HHS must gather some basic product information from stakeholders who would like to meet with federal government personnel. Stakeholders will register with MedicalCountermeasures.gov and answer a few basic questions regarding their product, and their product information will then be routed to the appropriate federal agency based on the routing criteria developed in an interagency working group. Members of the federal government will review the submitted information, and determine whether or not a meeting between industry and the government is appropriate at this time, and if so, with whom. To maximize efficiency, multiple agencies can coordinate joint meetings with one product developer. Participating agencies currently include: the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH).

The MedicalCountermeasures.gov web site will benefit all parties concerned by creating a structured, clear, centralized process for accessing the appropriate human resources at HHS, in place of the fragmented system which currently exists. Private industry stakeholders benefit by having a transparent, efficient, and central method of obtaining information and requesting meetings with government agencies. Government agencies benefit by being able to appropriately screen inquiries, track all meetings between industry and the various government agencies, efficiently manage requests for information from a central coordination point, and have a consistent method of record keeping. The use of a central government point of communication would greatly aid in reducing duplication of effort among agencies.

A. Justification

1. Need and Legal Basis

Currently, there is not a structured process for our stakeholders in industry and academia to communicate with the government. As a consequence, stakeholders are often unsure of which agencies they should be communicating with, and how to access appropriate personnel at these agencies. As a result, stakeholders often set-up meetings with personnel in government that cannot help meet their needs, which results in wasted time, both for stakeholders and for government personnel.

During roundtable discussions at the 2006 BioShield Stakeholders Workshop, stakeholders stressed the importance of access to the appropriate personnel within government. In the report titled *BioShield Stakeholders Workshop,* stakeholders indicated that: "The federal government needs to facilitate communication between different government organizations and help stakeholders navigate through government organizations to quickly find and work with appropriate points of contact" (9) (see **Appendix I**). MedicalCountermeasures.gov will promote communication both between stakeholders and the HHS. MedicalCountermeasures.gov will provide a clear, transparent method for industry to communicate with the government on issues related to medical countermeasures to intentional and naturally-occurring threats to public health.

The legal authority for ASPR to maintain the MedicalCountermeasures.gov website is derived from sections 301 and 2811 of the Public Health Service Act, and the website is in furtherance of Homeland Security Presidential Directive/HSPD-18: *Medical Countermeasures against Weapons of Mass Destruction*.

Section 301 of the Public Health Service Act (see **Appendix II**) empowers the Secretary of Health and Human Services to "encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man…" The Secretary of HHS has explicitly given his approval of this system during his statement before the 2006 BioShield Stakeholders Workshop. This system will promote research related to the treatment and control of naturally occurring and intentionally introduced diseases.

Section 2811 of the Public Health Service Act (see **Appendix III**) requires the Assistant Secretary for Preparedness and Response to "Oversee advanced research, development, and procurement of qualified countermeasures (as defined in section 319F-1) and qualified pandemic or epidemic products (as defined in section 319F-3)." As part of this responsibility, the ASPR is promoting activities that encourage communication between our stakeholders and the appropriate parts of the government.

In addition, this system furthers the goals of Homeland Security Presidential Directive/HSPD-18: *Medical Countermeasures against Weapons of Mass Destruction* (see **Appendix IV**). HSPD-18 states that: "The Secretary [of Health and Human Services] shall develop and implement a strategy to engage the unique expertise and capabilities of the private sector in developing medical countermeasures to combat WMD [Weapons of Mass Destruction]." This responsibility has been delegated to the Office of the Biomedical Advanced Research and Development Authority (BARDA). On July 5, 2007, BARDA published the *Draft BARDA Strategic Plan*, which indicates that BARDA plans to use the MedicalCountermeasures.gov as a key tool in facilitating communication between the government and external stakeholders.

2. Information Users

The information gathered from form submissions to MedicalCountermeasures.gov will be used as follows:

- Using pre-defined criteria developed in an interagency working group, MedicalCountermeasures.gov will route requests for meetings regarding medical countermeasures to naturally occurring and intentional threats to the appropriate person(s) in the correct federal agency(s).
- HHS will retain information gathered from this request to help it more accurately track the development of medical countermeasures to naturally occurring and manmade threats to public health. This data will help inform HHS planning efforts.

3. Improved Information Technology

Currently, external stakeholders call individual agencies, where points of contact are typically unclear and stakeholders often do not have a clear idea of the roles and responsibilities of different agencies. Often, companies engage lobbyists to help them navigate this system, which puts an increased burden on the companies. Additionally, incoming requests are currently not tracked, so it is impossible to tell whether or not external stakeholders are finding the help that they need. Given the feedback that was received at the 2006 BioShield Stakeholders Workshop, it appears that they are not. In the report titled *BioShield Stakeholders Workshop*, stakeholders indicated that: "The federal government needs to facilitate communication between different government organizations and help stakeholders navigate through government organizations to quickly find and work with appropriate points of contact" (9) (see **Appendix I**).

MedicalCountermeasures.gov uses information technology to reduce the administrative burden to both members of the federal government and external stakeholders. All submissions are made through the MedicalCountermeasures.gov website. External stakeholders fill out an on-line form, which is immediately sent into the MedicalCoutnermeasures.gov routing system. Rather than submitting information to

various agencies within HHS, stakeholders can now send their requests to one central location. The system routes meeting requests to federal employees, who then review the request and determine whether or not it is appropriate to meet with the federal government at this time. This is a significant improvement over the current process, which is fragmented and is not automated.

This system also allows HHS to examine user trends; determine whether or not there are stakeholders who have submitted requests, but have not received a response; and reduce the burden to our external stakeholders by giving them a clear and transparent system where they can submit requests for meetings.

4. Duplication of Similar Information

Currently, there is no formal process in place for submitting requests to the government for a meeting related to medical countermeasures to CBRN threats. As a result, companies often submit the same or similar information to multiple agencies. This system is designed to reduce paperwork by instituting a formalized system which enables companies to make one submission via an online form, which will be routed to all participating federal agencies. This represents a reduction in paperwork as compared to the current informal process.

The Stakeholders Portal Working Group, which includes participants from ASPR, CDC, FDA, and NIH, did not indicate that they were aware of any similar efforts. MedicalCountermeasures.gov was described to a room of 500 stakeholders from industry, academia, and government, and was received with enthusiasm at the government's attempt to streamline the existing process and make it more transparent. An internet search did not reveal any similar collection by the U.S. government.

5. Small Businesses

Data may be collected from small businesses, if there is a small business that is involved in the research and development of medical countermeasures to naturally occurring and/or intentional threats to public health. All submissions are completely voluntary, and all businesses, including small businesses, only need to submit the form if they are asking to meet with a representative of the federal government.

The submission is very simple for all entities, including small businesses. Request forms are targeted to different types of medical countermeasures, but all of the forms consist of less than 15 questions. During usability testing with users from our targeted stakeholder groups, it took our stakeholders less than 5 minutes to fill out each of the forms.

6. Less Frequent Collection

Submissions are made whenever a stakeholder would like to meet with the federal

government. They are completely voluntary and the frequency of the submission is based on the stakeholders' needs.

7. Special Circumstances

No special circumstances apply to this collection. However, ASPR recognizes that some of the supporting documentation that comes with a meeting request may be considered proprietary or trade-secret. MedicalCountermeasures.gov does not require submissions of proprietary or trade-secret information, but it does accept such information in support of a meeting request. The system does require submitters to appropriately mark all proprietary or trade secret information.

HHS has taken steps to secure this system that are in keeping with standards established by the National Institute of Standards and Technology (NIST) (most notably, NIST Special Publication 800-53 *Recommended Security Controls for Federal Information Systems* [see **Appendix V**]) and the Department of Health and Human Services (HHS) Certification and Accreditation Program. The system's security documentation must be reviewed by the HHS Office of the Chief Information Officer (OCIO), and judged by the OCIO to be in keeping with federal laws and best practices surrounding the security of information systems.

8. *Federal Register* Notice/Outside Consultation

The agency's 60-day notice appeared in the *Federal Register* Thursday**,** August 16, 2007, Vol. 72, No. 158, pp. 46062-46063, as required by 5 CFR 1320.8(d) (see **Attachment VI**). No public comments were received in response to the notice.

In October, 2006, BARDA convened the Stakeholders Portal Working Group to discuss issues related to the MedicalCountermeasures.gov system. This working group consisted of representatives from HHS (ASPR, CDC, FDA, and NIH), DOD, DHS, and VA. The working group discussed the specific information that the government needs to collect to route requests to the appropriate personnel, and developed a series of brief questionnaires designed to elicit the needed information from our stakeholders with minimal burden to the stakeholder.

On May 28 through June 1, 2007, HHS/BARDA brought in external stakeholders to participate in a series of individual usability tests of the system. In order not to inadvertently favor one group above another, we requested that BIO and the Center for Biosecurity choose some suitable testers. A third organization was contacted, but was unable to provide testers. The usability tests were developed and led by an external vendor with expertise in usability testing, and were conducted in the HHS Usability Lab. According to the report *Private Industry User (PIU) Usability Test Results*, "By and large, test participants found the system easy to navigate and use." Testers did make a number of suggestions to improve the site, which are being evaluated on a case-by-case

basis. The testers did not identify any major problems with the system.

On July 31-August 2, 2007, HHS/BARDA demonstrated the system to our stakeholders at the 2007 Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop via a hands-on exhibition booth. Participants who examined the website indicated that the questions were easy to understand, did not appear overly cumbersome, and were relevant to the topic being discussed. A formal survey was not taken, as the number of participants in the workshop was around 500, and we had not previously filed a Paperwork Reduction Act request. The 2007 PHEMC Enterprise Stakeholders Workshop included representatives from academia; industry; federal, state, and local governments; and the public health community.

9. Payment/Gift to Respondents

No payments or gifts were given to any of the respondents.

10. Confidentiality

The site does not explicitly use the word *confidential* with regard to a submission. Prior to the submission of product information, the submitter must accept the following statement:

> "Material submitted through this website is for information only. It is not a request for proposal (RFP) and does not commit the government to issue a solicitation, make a contract award, or pay any costs associated with responding to this announcement. All submitted information shall remain with the government and will not be returned. MedicalCountermeasures.gov does not accept unsolicited proposals, as described in FAR Subpart 15.6. Please submit unsolicited proposals directly to the appropriate federal agency.
>
> All regulatory submissions and requests to meet with FDA regarding regulatory issues (e.g., scheduling of any regulatory meetings) are to be submitted to FDA directly, not through the portal, and should follow applicable regulations and guidance for these matters.
>
> It is the responsibility of the submitter to mark all proprietary, confidential, or trade secret material appropriately. If you are submitting any of this material, please ensure that it is marked appropriately prior to submission. Please be aware that all authorized Site Administrators, Network Administrators, Agency Administrators, and Subject Matter Experts may have access to this information. This information is, however, not releasable to the Public.
>
> All submissions to MedicalCountermeasures.gov are voluntary and are for information only. However, the submission of complete information may facilitate

the routing of your request. The information that you have submitted will be kept on file with the government and will be available to relevant personnel in various agencies within the federal government."

As the purpose of the MedicalCountermeasures.gov meeting management system is for members of stakeholder groups to request a meeting from HHS (and other federal departments and agencies, should they choose to join), HHS must collect some personally identifying information in order to respond to the request. The system requires a username and password for security purposes, an e-mail address where the submitter may be contacted.

11. Sensitive Questions

MedicalCountermeasures.gov does not collect any information that is commonly considered private.

12. Burden Estimate (Total Hours & Wages)

Affected Public
Although improved public health emergency preparedness ultimately has a positive effect on all Americans, this system will most directly affect developers of medical countermeasures to naturally occurring and intentional threats. Product developers will be able to meet with the appropriate personnel in the federal government more easily. Improved communication will produce demonstrable benefits to both product developers and the federal government.

Number of Respondents and Number of Responses/Respondent:
As submissions to this system are completely voluntary, we have no concrete way of knowing how many respondents we may have. The estimate of 225 is based off of the number of stakeholders from the target group who signed up for the 2006 BioShield Stakeholders Workshop.

Submissions are voluntary and the government is not imposing a limitation on the number of times a respondent may submit a meeting request, but we anticipate that most respondents will only respond annually.

12A. Estimated Annualized Burden Hours:

Type of Respondent	Estimated Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Developers of medical countermeasures to naturally occurring and intentional public health threats.	225	1	8/60	30
Total		225		30

During usability testing, our external stakeholders took less than five minutes to complete this form. Allowing that the user may need to look up some additional information than is needed in a testing environment, the estimate is at eight minutes for a completed form.

As noted above, the estimate of 225 respondents is based off of the stakeholders who attended the 2006 BioShield Stakeholders Workshop who were in the target group.

12B. Estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. Although BARDA has no definite information on who will fill out the meeting request forms, we anticipate that it will be a mid- to high-level professional, as these are the people who often submit these requests through the current informal system.

Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Developers of medical countermeasures to naturally occurring and intentional public health threats.	8/60	$75.00	$10.00
Total			$2,250.00

13. Capital Costs: (Maintenance of Capital Costs)

There will be no new annual capital or maintenance costs to the respondent resulting from the collection of information for this project.

14. Cost to Federal Government

The estimate of average annual cost for data collection through the Stakeholder Portal for the period 2007 through 2010 is as follows:

Description	Cost
System Development (FY 2007)	$218,919.00
Security Test and Evaluation (FY2007-FY2008)	$57,260.00
Hosting and Maintenance: Year 1 (FY 2008)	$288,012.00
Hosting and Maintenance: Year 2 (FY 2009)	$296,553.78
Hosting and Maintenance: Year 3 (FY 2010)	$305,428.00
Total Cost	**$1,166,172.78**
Average Cost/Year	**$388,724.26**

15. Program or Burden Changes

This is a new data collection.

16. Publication and Tabulation Dates

As the primary purpose of the MedicalCountermeasures.gov system is to route meeting requests from external stakeholders to the appropriate personnel at HHS, little consideration has been paid to the publication of data that is gathered by this system. The data collection, which in this instance is only a tool used to route information to the appropriate personnel within the HHS, will begin within one month of receiving approval of the Paperwork Reduction Act request, and will continue indefinitely. However, as the Paperwork Reduction Act request only lasts for three years, the period of the collection will go on indefinitely, provided that HHS Paperwork Reduction Act requests on this topic continue to be approved.

Data gathered by this system may be published as a high-level general summary to demonstrate trends of medical countermeasures moving through the development pipeline as part of a technology watch report. However, no concrete plans exist at this time to publish the material.

17. Expiration Date

BARDA is requesting an exemption for displaying the expiration date of the Paperwork Reduction Act Request, as displaying the expiration date of the request may confuse

stakeholders. If an expiration date of the request is displayed, it may confuse our stakeholders, who may take it as an expiration date of their ability to submit a request to the government for discussion of their product.

18. <u>Certification Statement</u>

The data encompassed by this project will fully comply with all guidelines of 5 CFR 1320.9 and no exception is requested to certification for Paperwork Reduction Act Submission.

B. Collection of Information Employing Statistical Methods If statistical methods will not be used to select respondents and item 17 on Form 83-I is checked "No" use this section to describe data collection procedures.

Statistical methods will not be used to select respondents.

As the primary purpose of this system is to collect data from the external stakeholders to use in routing a request, data will come from external stakeholders who voluntarily submit meeting requests to the system and the submission of data will be ongoing. Data will be submitted by stakeholders via an online form and submissions will occur as often as the requestor believes it is necessary to meet with the government.