holidays. The telephone number for the Public Reading Room is 202–566–1744. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–ORD–2006–0666. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Note: The EPA Docket Center suffered damage due to flooding during the last week of June 2006. The Docket Center is continuing to operate. However, during the cleanup, there will be temporary changes to Docket Center telephone numbers, addresses, and hours of operation for people who wish to make hand deliveries or visit the Public Reading Room to view documents. Consult EPA's **Federal Register** notice at 71 FR 38147 (July 5, 2006) or the EPA Web site at *www.epa.gov/epahome/dockets.htm* for current information on docket operations, locations and telephone numbers. U.S. mail and the procedures for submitting comments to *www.regulations.gov* are not affected by the flooding and will remain the same.

Dated: September 7, 2006.

Peter W. Preuss,

Director, National Center for Environmental Assessment.

[FR Doc. E6–15335 Filed 9–14–06; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

International Development of H5N1 Influenza Vaccines; Funding Opportunity

AGENCY: Office of the Secretary, Office of Public Health Emergency Preparedness.

ACTION: Notice.

Funding Opportunity Title: International Development of H5N1 Influenza Vaccines.

Announcement Type: Single-Source Cooperative Agreement.

Catalog of Federal Domestic Assistance Number: The Office of Management and Budget (OMB) Catalog of Federal Domestic Assistance number is 93.019.

SUMMARY: The objective of this project is to mitigate any potential global shortage of influenza vaccines and the manufacturing of this vaccine in the event of an influenza pandemic. The Office of Public Health Emergency Preparedness (OPHEP) requires the World Health Organization (WHO) to perform activities related to pandemic influenza preparedness and planning, particularly in the international development of H5N1 human vaccines (and other pandemic influenza vaccine candidates) and influenza vaccine manufacturing infrastructure building in countries where resources for vaccine acquisition and manufacturing may be limited. The specific countries in which the WHO Secretariat will carry out these activities are Argentina, Brazil, India, Indonesia, Mexico, Romania, Russia, South Africa, and Tunisia. Activities include pre-clinical safety and immunogenicity testing, toxicology testing, clinical vaccine lot manufacturing, scale-up and process development, analytical lot release assay development and validation, and clinical immunogencity assay development and validation.

DATES: To receive consideration, applications must be received no later than 5 p.m., Eastern Time, on September 29, 2006.

ADDRESSES: The Office of Grants Management within the Office of Public Health and Science of the U.S. Department of Health and Human Services, located at 1101 Wootten Parkway, Rockville, MD 20857, must receive all applications.

SUPPLEMENTARY INFORMATION: In the last century, three influenza pandemics have struck the United States and the world, and viruses from birds contributed to all of them. In 1918, the first pandemic infected one-third of the U.S. population, killed over half a million Americans, reduced American life expectancy by 13 years, and killed more than 20 million people worldwide. Following the 1918 outbreak, influenza pandemics in 1957 and 1968 also killed tens of thousands of Americans and millions across the world. The recent limited outbreak of Severe Acute Respiratory Syndrome (SARS) in 2003 suggests the danger that a modern pandemic would present.

The H5N1 strain of avian influenza has become the most threatening influenza virus in the world, and any large scale outbreak of this disease among humans would have grave consequences for global public health. Influenza experts have warned that the reassortment of different H5N1 viruses over the past seven years greatly increases the potential for the viruses to be transmitted more easily from person to person. Medical practitioners have also discovered several other, new avian viruses that can be transmitted to humans.

The U.S. Government is concerned that a new influenza virus could become efficiently transmissible among humans. Now spreading through bird populations across Asia, reaching into Europe, the Middle East and, most recently, Africa, the H5N1 strain has infected domesticated birds, such as ducks and chickens, and long range migratory birds. In 1997, the first recorded H5N1 outbreak in humans took place in Hong Kong. H5N1 struck again in late 2003, and has, as of August 17, 2006, resulted in 239 confirmed cases and 140 deaths world-wide, a 59 percent mortality rate. As of now, the H5N1 avian influenza is primarily an animal disease; H5N1 infection in humans has been the result of contact with sick poultry. Unless people come

into direct, sustained contact with infected birds, it is unlikely they will contract the disease. The concern is that the virus will acquire the ability for sustained transmission among humans.

Equally alarming is that the global influenza vaccine manufacturing capacity of 400–500 million doses of vaccine per year is far short of the needed 4–8 billion doses that may be needed to protect the global population. Influenza vaccine manufacturers are located primarily in industrialized countries and provide vaccine to these countries. However, other countries lack the resources to procure influenza vaccine from the commercial providers and/or are devoid of the necessary vaccine manufacturing infrastructure needed to produce pandemic influenza vaccine in-country.

In November, 2005, U.S. President George W. Bush directed all relevant Federal Departments and agencies to take steps to address the threat of avian and pandemic influenza. Drawing on the combined efforts of Government officials and the public health, medical, veterinary, and law enforcement communities, as well as the private sector, this strategy is designed to meet three critical goals: detecting human or animal outbreaks that occur anywhere in the world; protecting the American people by stockpiling vaccines and antiviral drugs, while improving the capacity to produce new vaccines; and preparing to respond at the Federal, State, and local levels in the event an avian or pandemic influenza reaches the United States.

One of the primary objectives of the U.S. Government's international efforts on avian and pandemic influenza preparations is to pursue and develop global partnerships to increase preparedness and response capabilities around the world with the intent of stopping, slowing or otherwise limiting the spread of a pandemic to the United States. These efforts include goals of ensuring the rapid reporting of outbreaks and containing such outbreaks beyond the borders of the United States, by taking the following actions:

- Work through multilateral health organizations such as the World Health Organization (WHO), the United Nation's Food and Agriculture Organization (FAO), the World Organization for Animal Health (OIE), and regional organizations such as the Asia-Pacific Economic Cooperation (APEC) forum, as well as through bilateral and multilateral contacts, to do the following:
- Support the development and exercising of avian-influenza and pandemic-response plans;
- Expand in-country medical, veterinary and scientific capacity to respond to an outbreak;
- Educate populations at home and abroad about high-risk practices that increase the likelihood of virus transmission between species;
- Encourage nations to develop production capacity and stockpiles to support their response needs, to include the pooling of efforts to create regional capacity;
- Ensure that there is maximal sharing of scientific information about influenza viruses between Governments, scientific entities and the private sector;
- Work with our international partners to ensure we are all leveraging the most advanced technological approaches available for vaccine production;
- Work through the International Partnership on Avian and Pandemic Influenza to develop a coalition of strong partners to coordinate actions to limit the spread of a virus with pandemic potential beyond the location where it is first recognized to protect U.S. interests abroad; and
- Where appropriate, offer and coordinate assistance from the United States and other members of the International Partnership.

Through such partnerships other bilateral and multilateral initiatives, we will promote these principles and support the development of an international capacity to prepare, detect and respond to an influenza pandemic. For example, the WHO global action plan promotes increased capacity for production of human influenza pandemic vaccines to reduce the anticipated gap between the potential vaccine demand and supply during an influenza pandemic.

This announcement seeks to support increased access to vaccines by stimulating influenza vaccine development and manufacturing infrastructure building by institutions in foreign countries as they develop sustainable programs for vaccines to prevent avian H5N1 or other influenza viruses in humans.

Within the U.S. Department of Health and Human Services (HHS), the Office of Public Health Emergency Preparedness (OPHEP) intends to award to the WHO Secretariat a maximum grant award of $10,000,000. OPHEP may award subsequent grants or cooperative agreements in future fiscal years for international development of H5N1 vaccine (or other pandemic vaccine candidates), in the event OPHEP receives congressional authority and funding.

Only the Secretariat of the World Health Organization is eligible to submit an application for this funding opportunity.

Other funds the WHO Secretariat chooses to provide for such efforts, within the WHO Pandemic Influenza Framework may support similar program efforts in other, additional countries or complementary activities in the same countries.

I. Funding Opportunity Description

Authority: The Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico and Pandemic Influenza Act, 2006, Pub. L. 109–148 119 Stat. 2680, 2786 (2005).

Purpose: The purposes of the award are to do the following:

- Support the production of candidate vaccines, in the countries specified, to prevent the H5N1 strain of influenza in humans, under proper biosafety and quality conditions, for clinical trials;
- Provide funding for the development and manufacturing of human vaccine candidates against the H5N1 strain of highly pathogenic avian influenza and the establishment of pilot production and commercial-scale vaccine manufacturing processes for non-(pre)clinical safety and immunogenicity testing that could lead to regulatory approval or licensure of a human H5N1 vaccine by national regulatory authorities in the specified countries for the prevention of H5N1 influenza virus infection in humans; and
- Develop inactivated H5N1 vaccines by using eggs or qualified cells or cell lines and a virus reassortant qualified by the WHO that contains HA and NA genes derived from a recent human H5N1 influenza strain.

Measurable Outcomes

Measurable outcomes of the program will be in alignment with the U.S. President's *National Strategy for Pandemic Influenza* and the principles of the International Partnership on Avian and Pandemic Influenza, and one (or more) of the following performance goal(s) for HHS pursuant to the U.S. President's initiative on pandemic-influenza preparedness:

- Prevent and contain an incipient epidemic through capacity building and in-country collaboration with international partners;
- Work in a manner complementary to and supportive of expanded cooperation with and appropriate

support of key multilateral organizations (including the WHO, the FAO and the OIE);

• Timely coordination of bilateral and multilateral resource allocations; dedication of domestic resources (human and financial); improvements in public awareness; and development of economic and trade contingency plans; and/or

• Increased coordination and harmonization of preparedness, prevention, response and containment activities among nations, complementing domestic and regional preparedness initiatives, and encouraging where appropriate the development of strategic regional initiatives, and actions based on the best available science.

Grantee Activities

Grantee activities for this award are as follows:

• Perform activities related to pandemic influenza preparedness and planning, particularly in the international development of H5N1 human vaccines (and other pandemic influenza vaccine candidates) and influenza vaccine manufacturing infrastructure building in countries where resources for vaccine acquisition and manufacturing may be limited. The specific countries in which the WHO Secretariat will carry out these activities are Argentina, Brazil, India, Indonesia, Mexico, Romania, Russia, South Africa, and Tunisia. Activities include pre-clinical safety and immunogenicity testing, toxicology testing, clinical vaccine lot manufacturing, scale-up and process development, analytical lot release assay development and validation, and clinical immunogencity assay development and validation. All procurement transactions or contracts entered into by the WHO shall be conducted in a manner to provide, to the maximum extent practical, open and free competition for public sector and private sector entities in the target countries. The recipient shall be alert to organizational conflicts of interest as well as noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade.

• Undertake relevant activities to develop standard methods and reagents;

• Conduct periodic, site visits, with international experts;

• Ensure work supported by these grants complies with WHO biosafety guidelines for pandemic-influenza vaccine manufacturing and acceptable to the relevant national regulatory agency;

• Provide H5N1 virus reference vaccine strains from WHO influenza virus reference laboratories; and

• Provide WHO potency reagent standards, including virus reference antigen and antiserum, for lot-release testing of human vaccines against the H5N1 strain.

Activities not eligible for funding include the following:

• Study design, implementation, and analysis of clinical trials; and

• Preparation of vaccine candidates for licensure by a country's national regulatory agency.

HHS Activities for this program are as follows:

1. Participate in an orientation meeting with the grantee on expectations, regulations and key management requirements, as well as reporting requirements and formats and contents. The orientation could include staff from HHS agencies and the Office of the Special Representative for Avian and Pandemic Influenza at the U.S. Department of State.

2. Provide the WHO Secretariat with the necessary resources and expert assistance in specialized training areas.

All influenza virus information obtained or developed as a result of the foregoing activities or other activities funded under this cooperative agreement shall be shared with HHS, the WHO Global Influenza Network, and WHO Collaborating Centers of Influenza, and placed in the public domain, worldwide. If the WHO Secretariat enters into contracts or other agreements to accomplish the requirements of this cooperative agreement, WHO shall include language in such contracts and agreements stating that any information obtained or developed as a result of the foregoing activities or other activities funded under this cooperative agreement shall be shared with HHS, the WHO Global Influenza Network, and WHO Collaborating Centers of Influenza and placed within the public domain, worldwide. The WHO Secretariat shall also include language in said contracts or agreements that makes the United States Federal Government a third-party beneficiary to any information obtained or developed as a result of the foregoing activities or other activities funded under this cooperative agreement.

II. Award Information

This project will be supported through the cooperative agreement mechanism. HHS anticipates making only one award. The period of performance is September 15, 2006 through September 14, 2007.

Approximate Current Fiscal Year Funding: $10,000,000.

III. Eligibility Information

1. Eligible Applicant

The WHO Secretariat is the only worldwide organization with the experience and scientific standing to accomplish the goals set forth in this RFA. It is the recognized world health authority within the United Nations system. It has over 40 years of experience in establishing and monitoring vaccine programs. The WHO has established a pandemic influenza program that includes disease-surveillance, assistance with vaccine production, and through its unique system of WHO Collaborating Laboratories, the technical expertise to recommend and supply unique and relevant reagents necessary for the production and characterization of pandemic influenza vaccines. There is no other organization with this history and capability.

Program efforts in other and additional countries may be supported by other funds the WHO Secretariat chooses to provide for such efforts, within the WHO Pandemic Influenza Framework.

2. Cost-sharing or Matching Funds

Matching funds are not required for this program. Although matching funds are not required, preference may go to organizations that can leverage additional funds to contribute to program goals.

3. Special Requirements

If the application is incomplete or non responsive to the special requirements listed in this section, the application will not enter into the review process. HHS will notify the applicant that the application did not meet submission requirements.

• HHS will consider a late application to be nonresponsive. Please see section on Submission Dates and Times.

• Section 503, Departments of Labor, Health and Human Services, Education and related agencies, Appropriations Act, 2006, Pub. L. 109–149, 119 Stat. 2833, which states that appropriated funds under the Act shall not be used for lobbying activities, applies.

IV. Application and Submission Information

1. Address To Request Application Package

Applicants may request application kits by calling 1-(240) 453 8822, or by writing to the Office of Grants

Management, Office of Public Health and Science, U.S. Department of Health and Human Services, 1101 Wootten Parkway, Suite 550, Rockville, MD 20852. Applicants may also fax a written request to the HHS/OPHS Office of Grants Management at 1–(240) 453 8823 to obtain a hard copy of the application kit. Applicants must prepare their applications by using Form OPHS 1.

2. Content and Form of Submission

Application: Applicants must submit a project narrative in English, along with the application forms, in the following format:

- *Maximum number of pages:* 50. If your narrative exceeds the page limit, HHS will only review the first 50 pages within the page limit;
- *Font size:* 12-point, unreduced;
- Single-spaced;
- *Paper size:* 8.5 by 11 inches;
- *Page margin size:* One inch;
- Number all pages of the application sequentially from page one (i.e., the Application Face Page) to the end of the application, including charts, figures, tables, and appendices;
- Print only on one side of page; and
- Hold application together only by rubber bands or metal clips, and do not bind it in any way.

The narrative should address activities over the entire project period, and must include the following items, in the order listed:

A. Understanding of the Requirements.

The application shall include a discussion of your organization's understanding of the need, purpose and requirements of this cooperative agreement, as well as the U.S. President's National Strategy and the principles of the International Partnership on Avian and Pandemic Influenza. The discussion shall be sufficiently specific, detailed and complete to clearly and fully demonstrate that the applicant has a thorough understanding of all the technical requirements of this announcement.

The applicant must describe how it will perform the requirements (meet the goals) in this RFA. The applicant must include a description of what standards will be used to measure the effectiveness and accomplishments of the requirements in the cooperative agreement. Measures must be objective and quantitative, and must measure the intended outcomes. The applicant must submit a section on measures of effectiveness with its application, and they will be an element for evaluation.

B. Project Plan

Background and Significance:

- Describe the background and justify the need for the proposed project to enhance or expand the development and manufacturing of human candidate vaccines against the H5N1 strain of influenza in the targeted countries.
- Applicants must provide timelines, milestones (as appropriate) and address specific areas of risk, such as scientific, facility, regulatory and mitigation plans to ensure timely completion of the project.

C. Staffing and Management Plan

The applicant must provide a project staffing and management plan, which must include time lines and sufficient detail to ensure that it can meet the Federal Government's requirements in a timely and efficient manner. The applicant must provide résumés that identify the educational and experience level of any individual(s) who will perform in a key position and other qualifications to show the key individuals' ability to comply with the minimum requirements of this announcement. The applicant must provide a summary of the qualifications of non key personnel. Résumés must be limited to three pages per person.

The proposed staffing plan must demonstrate the applicant's ability to recruit, retain, and replace personnel who have the knowledge, experience, local language skills, training and technical expertise commensurate with the requirements of this announcement. The plan must demonstrate the applicant's ability to provide bilingual personnel to train and mentor host country participants.

D. Budget Justification

The budget justification, limited to 10 pages, will count against the overall 50-page application limit. This justification must comply with the criteria for applications. The applicant must submit, at a minimum, a cost proposal fully supported by information adequate to establish the reasonableness of the proposed amount.

The applicant may include additional information in the application appendices, which will not count toward the narrative page limit. This additional information may include Curricula Vitae, Résumés, Organizational Charts, Letters of Support, etc.

An agency or organization must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, access the following Internet address, *http://www.dunandbradstreet.com*, or call 1 866 705 5711.

Additional requirements that could require submission of additional documentation with the application appear in Section VI.2, ''Administrative and National Policy Requirements.''

3. Submission Dates and Times

To be considered for review, applications must be received by the HHS/OPHS Office of Grants Management by 5 p.m., Eastern Time on the date specified in the dates section of the announcement. HHS will consider applications as having met the deadline if we receive them on or before the deadline date. The application due date in this announcement supersedes the instructions in the OPHS 1.

Submission Mechanisms

HHS/OPHS, which is serving as the awarding agency for HHS/OPHEP, provides multiple mechanisms for the submission of applications, as described in the following sections. Applicants will receive notification via mail from the HHS/OPHS Office of Grants Management to confirm the receipt of applications submitted by using any of these mechanisms. HHS will not accept applications submitted to the HHS/OPHS Office of Grants Management after the deadlines identified below. HHS will not accept for review applications that do not conform to the requirements of the cooperative agreement announcement, and will return such applications to the applicant.

Applicants may submit electronically only via the electronic submission mechanisms specified below. HHS will not accept any applications submitted via any other means of electronic communication, including facsimile or electronic mail. While HHS will accept applications in hard copy, we encourage the use of the electronic application submission capabilities provided by the HHS/OPHS eGrants system or the *http://www.Grants.gov* Web site Portal.

Applicants must submit electronic grant applications no later than 5 p.m., Eastern Time, on the deadline date specified in the ''Submission Dates and Times'' section of this announcement, by using one of the electronic submission mechanisms specified below. The HHS/OPHS Office of Grants Management must receive all required

hard-copy original signatures and mail in items by no later than 5 p.m., Eastern Time, on the next business day after the deadline date specified in the ''Submission Dates and Times'' section of this announcement.

HHS will not consider applications as valid until the HHS/OPHS Office of Grants Management has received all electronic application components, hard-copy original signatures, and mail in items according to the deadlines specified above. HHS will consider as late application submissions that do not adhere to the due date requirements, and will consider them ineligible.

HHS encourages applicants to initiate electronic applications early in the application development process, and to submit prior to or early on the due date. This will allow sufficient time to address any problems with electronic submissions prior to the application deadline.

Electronic Submissions via the HHS/OPHS eGrants System

The HHS/OPHS electronic grants-management system, eGrants, provides for the electronic submission of applications. Information about this system is available on the OPHS eGrants Web site, at the following Internet address: *https://egrants.osophs.dhhs.gov*; or interested parties may request it from the HHS/OPHS Office of Grants Management at 1–(240) 453B8822.

When submitting applications via the HHS/OPHS eGrants system, applicants must submit a hard copy of the application face page (Standard Form 424) with the original signature of an individual authorized to act for the applicant agency and assume the obligations imposed by the terms and conditions of the grant award. If required, applicants will also need to submit a hard copy of the Standard Form LLL and/or certain Program-related forms (e.g., Program Certifications) with the original signature of an individual authorized to act for the applicant agency.

Electronic applications submitted via the HHS/OPHS eGrants system must contain all completed online forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. The applicant may identify specific mail in items to send to the HHS/OPHS Office of Grants Management separate from the electronic submission; however, applicants must enter these mail in items on the eGrants Application Checklist at the time of electronic submission, and HHS/OPHS must receive them by the due date requirements specified above. Mail-in items may only include publications, résumés, or organizational documentation.

Upon completion of a successful electronic application submission, the HHS/OPHS eGrants system will provide the applicant with a confirmation page to indicate the date and time (Eastern Time) of the electronic application submission. This confirmation page will also provide a listing of all items that constitute the final application submission, including all electronic application components, required hard-copy original signatures, and mail-in items, as well as the mailing address of the HHS/OPHS Office of Grants Management to which applicants must submit all required hard-copy materials.

As the HHS/OPHS Office of Grants Management receives items, it will update the electronic application status to reflect the receipt of mail-in items. We recommend applicants monitor the status of their applications in the HHS/OPHS eGrants system to ensure we have received all signatures and mail in items.

Electronic Submissions via the *http://www.Grants.gov* Web site Portal

The Grants.gov Web site Portal provides organizations with the ability to submit applications for HHS/OPHS grant opportunities. Organizations must successfully complete the necessary registration processes to submit an application. Information about this system is available on the Grants.gov Web site, at the following Internet address: *http://www.grants.gov*.

In addition to electronically submitted materials, applicants may be required to submit hard-copy signatures for certain program-related forms, or original materials as required by the announcement. Applicants must review both the cooperative agreement announcement as well as the application guidance provided within the Grants.gov application package to determine such requirements. Applicants must submit separately any required hard-copy materials or documents that require a signature via mail to the HHS/OPHS Office of Grants Management, and which, if required, must contain the original signature of an individual authorized to act for the applicant agency and to assume the obligations imposed by the terms and conditions of the cooperative agreement award.

Electronic applications submitted via the Grants.gov Web site Portal must contain all completed online forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. HHS must receive all required mail in items by the due date specified above. Mail-in items may only include publications, résumés or organizational documentation.

Upon completion of a successful electronic application submission via the Grants.gov Web site Portal, the applicant will receive a confirmation page from Grants.gov to indicate the date and time (Eastern Time) of the electronic application submission, as well as the Grants.gov Receipt Number. It is critical that the applicant print and retain this confirmation, as well as a copy of the entire application package for its records. Grants.gov will validate all applications submitted via the Grants.gov Web site Portal. Any applications deemed invalid by the Grants.gov Web site Portal will not be transferred to the HHS/OPHS eGrants system, and HHS/OPHS has no responsibility for any application not validated and transferred to HHS/OPHS from the Grants.gov Web site Portal. Grants.gov will notify the applicant regarding the application validation status. Once the Grants.gov Web site Portal has successfully validated an application, applicants should immediately mail all required hard-copy materials to the HHS/OPHS Office of Grants Management by the deadlines specified above. It is critical the applicant clearly identify the Organization name and Grants.gov Application Receipt Number on all hard-copy materials.

Once Grants.gov has validated an application, it will be proceed electronically to the HHS/OPHS eGrants system for processing. Upon receipt of both the electronic application from the Grants.gov Web site Portal, and the required hard-copy mail in items, applicants will receive notification via mail from the HHS/OPHS Office of Grants Management to confirm the receipt of the application submitted through the Grants.gov Web site Portal.

Applicants should contact Grants.gov regarding any questions or concerns about the electronic application process used by the Grants.gov Web site Portal.

Mailed or Hand-Delivered Hard-Copy Applications

Applicants who submit applications in hard copy (via mail or hand delivered) must submit an original and two copies of the application. An individual authorized to act for the applicant agency or organization and to assume for the organization the obligations imposed by the terms and conditions of the grant award must sign the original application.

HHS will consider mailed or hand delivered applications will be considered as having met the deadline if the HHS/OPHS Office of Grant Management receives them on or before 5 p.m., Eastern Time, on the deadline date specified in the ''Submission Dates and Times'' section of this announcement. The application deadline date requirement specified in this announcement supersedes the instructions in the OPHS 1. HHS will return to the applicant, unread, applications that do not meet the deadline.

4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

5. Funding Restrictions

Restrictions, which applicants must take into account while preparing the budget, are as follows:

- Alterations and renovations (A&R) are prohibited on grants/cooperative agreements to foreign recipients. ''Alterations and renovations'' are defined as work that changes the interior arrangements or other physical characteristics of an existing facility or of installed equipment so that it can be used more effectively for its currently designated purpose or adapted to an alternative use to meet a programmatic requirement. Recipients may not use funds for A&R (including modernization, remodeling, or improvement) of an existing building.
- Recipients may not use funds for planning, organizing or convening conferences.
- Reimbursement of pre-award costs is not allowed.
- Recipients may spend funds for reasonable program purposes, including personnel, travel, supplies, and services. Recipients may purchase equipment if deemed necessary to accomplish program objectives; however, they must request prior approval in writing from HHS/OPHEP officials for any equipment with a purchase price in excess of $10,000 USD.
- The costs generally allowable in grants/cooperative agreements to domestic organizations are allowable to foreign institutions and international organizations, with the following exception: With the exception of the American University, Beirut and the WHO Secretariat, HHS will not pay indirect costs (either directly or through sub award) to organizations located outside the territorial limits of the United States, or to international organizations, regardless of their location.
- Recipients may contract with other organizations under this program; however, the applicant must perform a substantial portion of the project activities (including program management and operations) for which it is requesting funds and the recipient remains responsible for all funds under the award. Contracts will require prior approval in writing from HHS/OPHEP.
- Recipients may not use funds awarded under this cooperative agreement to support any activity that duplicates another activity supported by any component of HHS.
- Applicants shall state all requests for funds in the budget in U.S. dollars. Once HHS makes an award, HHS will not compensate foreign recipients for currency exchange fluctuations through the issuance of supplemental awards.
- The funding recipient must obtain annual audits of these funds (program specific audit) by a U.S. based audit firm with international branches and current licensure/authority in country, and in accordance with International Accounting Standards or equivalent standard(s) approved in writing by HHS.
- A fiscal Recipient Capability Assessment may be required, prior to or post award, to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.

6. Other Submission Requirements

None.

V. Application Review Information

1. Criteria

HHS will evaluate applications against the following factors:

Factor 1: Does the application reflect a thorough understanding of the RFA and provide an acceptable plan for the accomplishment of these requirements including detailing the process for procurement transactions or contracts to ensure, to the maximum extent practical, open and free competition for public sector and private sector entities in the target countries? (50 points)

Factor 2: Does the applicant have an established Pandemic Influenza program that includes disease surveillance, and assistance in vaccine production, and does it have the technical expertise to be able to recommend and supply relevant reagents? (25 points)

Factor 3: Does the applicant have a successful history in working with the United States Government and the U.S. Department of Health and Human Services (HHS) on pandemic influenza issues? (25 points)

2. Review and Selection Process

HHS/OPHEP will review applications for completeness. An incomplete application or an application that is non responsive to the eligibility criteria will not advance through the review process. HHS will notify applicants if their applications did not meet submission requirements.

An objective review panel, which could include both Federal employees and non Federal members, will evaluate complete and responsive applications according to the criteria listed in Section V.1, ''Criteria,'' above.

VI. Award Administration Information

1. Award Notices

The successful applicant will receive a Notice of Award (NoA). The NoA shall be the only binding, authorizing document between the recipient and HHS. An authorized Grants Management Officer will sign the NoA, and mail it to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

2. Administrative and National Policy Requirements

A successful applicant must comply with the administrative requirements set forth in 45 CFR part 74 and part 92 as appropriate. The Fiscal Year 2006 Appropriations Act requires that when issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, the issuance shall clearly state the percentage and dollar amount of the total costs of the program or project financed with Federal money, and the percentage and dollar amount of the total costs of the project or program that will be financed by non governmental sources.

3. Reporting Requirements

The applicant must provide The Grants Management Specialist at HHS listed in the ''Agency Contacts'' section of this announcement with an original, plus two hard copies, as well as an electronic copy of the following reports in English:

1. A quarterly progress report, due no less than 30 days after the end of each quarter of the budget period. The quarterly progress report must contain the following elements:

a. Activities and Objectives for the Current Budget Period;

b. Financial Progress for the Current Budget Period;

c. Proposed Activity Objectives for the New Budget Period;

d. Budget;

e. Measures of Effectiveness; and

f. Additional Requested Information.

2. An annual progress report, due 90 days after the end of the budget period, which must contain a detailed summary of the elements required in the quarterly progress report;

3. Final performance reports, due no more than 90 days after the end of the project period; and

4. A Financial Status Report (FSR) SF 269 is due 90 days after the close of each 12 month budget period.

Recipients must mail the reports to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For program technical assistance, contact the following:

Robin A. Robinson, Ph.D., Associate Director (Acting) for Medical Counter Measures Programs (Influenza), Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness, U.S. Department of Health and Human Services, 330 Switzer Bldg., Room 1512, 330 C Street, SW., Washington, DC 20201, (202) 205–3931 office, (202) 205–3915 fax, e-mail: *robin.robinson@hhs.gov.*

Andrew Robertson, Ph.D., Office of Public Health Emergency Preparedness, U.S. Department of Health and Human Services, 200 Independence Avenue, SW., Room 638G, Washington, DC 20201, (202) 401–5839, (202) 690–6512, e-mail: *andrew.robertson@hhs.gov.*

For financial, grants management, or budget assistance, contact:

DeWayne Wynn, Grants Management Specialist, Office of Grants Management, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootten Parkway, Suite 550, Rockville, MD 20857, telephone: (240) 453–8822, e-mail address: *DeWayne.Wynn.os@hhs.gov.*

Dated: September 11, 2006.

W. Craig Vanderwagen,

Assistant Secretary for Public Health Emergency Preparedness, U.S. Department of Health and Human Services.

[FR Doc. E6–15325 Filed 9–14–06; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–38 and CMS–R–96]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Conditions of Certification for Rural Health Clinics and Supporting Regulations in 42 CFR 491.9, 491.10, 491.11; *Use:* The Rural Health Clinic (RHC) conditions of participation are based on criteria prescribed in law and are designed to ensure that each facility has a properly trained staff to provide appropriate care and to assure a safe physical environment for patients. The Centers for Medicare and Medicaid Services (CMS) uses these conditions of participation to certify RHCs wishing to participate in the Medicare program. These requirements are similar in intent to standards developed by industry organizations such as the Joint Commission on Accreditation of Hospitals, and the National League of Nursing/American Public Association and merely reflect accepted standards of management and care to which rural health clinics must adhere. *Form Number:* CMS–R–38 (OMB#: 0938–0334); *Frequency:* Recordkeeping and Reporting—Annually and upon initial application for Medicare approval; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 3,674; *Total Annual Responses:* 3,674; *Total Annual Hours:* 8,816.

2 *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Emergency and Foreign Hospital Services—Beneficiary Statement of Canadian Travel Claims and Supporting Regulations in 42 CFR 424.123; *Use:* The emergency services furnished a beneficiary outside the U.S. are covered under Medicare if the foreign hospital meets the conditions for a domestic nonparticipating hospital in addition to one of the following: (1) If the emergency is considered to have occurred within the U.S. and the reason for departure for the U.S. was to obtain treatment; (2) if the emergency occurred in Canada while the beneficiary was traveling between Alaska and another State; (3) if the Canadian or Mexican hospital is closer, more accessible or adequately equipped to handle the illness or injury; or (4) services were rendered aboard a ship in an American port or on the same day the ship arrived or departed from that port. *Form Number:* CMS–R–96 (OMB#: 0938–0484); *Frequency:* Reporting—On occasion; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 1,100; *Total Annual Responses:* 1,100; *Total Annual Hours:* 275.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395–6974.

Dated: September 8, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–15307 Filed 9–14–06; 8:45 am]

BILLING CODE 4120–01–P