proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on July 27, 2009.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: June 18, 2009.

Michelle Shortt,

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

[FR Doc. E9–15189 Filed 6–25–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NCCAM Customer Service Data Collection

Summary: 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 National Center for Complementary and Alternative Medicine (NCCAM), at the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: NCCAM Customer Service Data Collection. *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* NCCAM provides the public, patients, families, health care providers, complementary and alternative medicine (CAM) practitioners, and others with the latest scientifically based information on CAM and information about NCCAM's programs through a variety of channels, including its toll-free telephone information service and its quarterly newsletter. To ensure that NCCAM is effectively serving all audiences, NCCAM needs to continue to measure customer satisfaction with NCCAM telephone interactions. This effort involves a telephone survey consisting of 10 questions, which are asked of 25 percent of all callers, for an annual total of approximately 1,210 respondents. NCCAM uses the data collected from the surveys to characterize NCCAM users and help program staff measure user satisfaction, assess impact of their communication efforts, tailor services to the public and health care providers, measure service use among special populations, and assess the most effective media and messages to reach these audiences. *Frequency of Response:* Once. *Affected Public:* Individuals and households. *Type of Respondents:* Patients, spouses/family/friends of patients, health care providers, physicians, CAM practitioners, or other individuals contacting the NCCAM Clearinghouse.

The annual reporting burden is as follows.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Telephone survey: Individuals or households	1,210	1	0.075	91

The annualized cost to respondents is estimated at $1,770 for the telephone survey. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information Contact: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Christy Thomsen, Director, Office of Communications and Public Liaison, NCCAM, 31 Center Drive, Room 2B11, Bethesda, MD 20892–2182; or fax your request to 301–402–4741; or e-mail *thomsenc@mail.nih.gov*. Ms. Thomsen can be contacted by telephone at 301–451–8876.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: June 18, 2009.

Christy Thomsen,

Director, Office of Communications and Public Liaison, National Center for Complementary and Alternative Medicine, National Institutes of Health.

[FR Doc. E9–15058 Filed 6–25–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0264]

Amended Authorization of Emergency Use of Doxycycline Hyclate Tablet Emergency Kits for Eligible United States Postal Service Participants in the Cities Readiness Initiative and Their Household Members; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the Emergency Use Authorization (EUA) (the Authorization) for doxycycline hyclate tablet emergency kits for eligible U.S. Postal Service (USPS) participants in the Cities Readiness Initiative (CRI) and their household members issued on October 3, 2008, under the Federal Food, Drug, and Cosmetic Act (the act), as requested by the Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR),

Health and Human Services (HHS). Following issuance of FDA's October 3, 2008, Authorization letter, on February 19, 2009, BARDA submitted a request on behalf of ASPR, to amend the Authorization. In response to BARDA's request, FDA amended the Authorization letter and reissued the Authorization letter in its entirety on February 25, 2009. The Authorization, as amended and reissued in its entirety, is reprinted in this document.

DATES: The amended Authorization is effective as of February 25, 2009.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Amendment to the October 3, 2008, Authorization for Doxycycline Hyclate in Emergency Kits

On September 23, 2008, under section 564(b)(1)(A) of the the act (21 U.S.C. 360bbb-3(b)(1)(A)), as amended by the Project BioShield Act of 2004 (Public Law 108–276), the Secretary of Homeland Security determined that there is a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *Bacillus anthracis*. On October 1, 2008, under section 564(b) of the act, and on the basis of such determination, the Secretary of HHS, Michael O. Leavitt, declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a). Notice of the determination of the Secretary of Homeland Security and the declaration of the Secretary of HHS was published in the **Federal Register** on October 6, 2008 (73 FR 58242).

On October 1, 2008, BARDA requested an EUA for doxycycline hyclate tablet emergency kits for eligible USPS participants in CRI and their household members. As required under section 564(h)(1) of the act, on October 21, 2008, FDA published in the **Federal Register** notice of the Authorization for doxycycline hyclate tablet emergency kits for eligible USPS participants in the CRI and their household members, including an explanation of the reasons for its issuance (73 FR 62057, October 21, 2008). On February 19, 2009, BARDA submitted a request on behalf of ASPR to amend the Authorization to make certain changes to the written information authorized to accompany the doxycycline hyclate tablets and to the roles and responsibilities provided for in the Authorization. On February 25, 2009, in response to BARDA's request, FDA amended the Authorization letter and reissued the Authorization letter in its entirety.

II. Electronic Access

An electronic version of this notice and the full text of the Authorization are available on the Internet at *http://www.regulations.gov*.

III. The Authorization

After having consulted with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and having concluded that the criteria for issuance of this Authorization under section 564(c) of the act were met, on October 3, 2008, FDA authorized the emergency use of doxycycline hyclate tablet emergency kits for eligible USPS participants in the CRI and their household members. The letter of authorization in its entirety, as amended on February 25, 2009, follows:

February 25, 2009
Robin Robinson, Ph.D.
Director
Biomedical Advanced Research and Development Authority (BARDA)
330 Independence Avenue SW
Room G640
Washington, DC 20201
Dear Dr. Robinson:

This letter is in response to BARDA's October 1, 2008 submission, as amended,[1] requesting that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the pre-event provision and potential use of doxycycline hyclate tablet emergency kits[2] for inhalational anthrax, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act). Your request is specifically for eligible[3] United States Postal Service (USPS) participants in the Cities Readiness Initiative (CRI) (hereinafter USPS participants) and their household members.[4]

On September 23, 2008, pursuant to section 564(b)(1)(A) of the Act, 21 U.S.C. § 360bbb–3(b)(1)(A), the Secretary of the Department of Homeland Security determined that there is a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents--in this case, *Bacillus anthracis*.[5] On October 1, 2008, pursuant to section 564(b) of the Act, and on

[1] BARDA submitted an amendment on October 3, 2008. Following issuance of FDA's October 3, 2008, authorization letter, BARDA submitted a request on behalf of the Office of the Assistant Secretary for Preparedness and Response (ASPR) on February 19, 2009, to further amend the authorization. This amended authorization letter responds to that request.

[2] Your submissions refer to a Household Antibiotic Kit (HAK), which would be stored in an eligible United States Postal Service (USPS) participant's home and would contain unit-of-use bottles of doxycycline hyclate tablets (100 mg) and both emergency use instructions and home preparation instructions. Your submissions also refer to an individual Household Antibiotic Kit (iHAK), which would be stored at an eligible USPS participant's workplace and would contain only one unit-of-use bottle of doxycycline hyclate tablets (100 mg) and emergency use instructions. For ease of reference, this letter of authorization will use the term ''doxycycline hyclate tablet emergency kit(s)'' to refer to both types of kits, unless otherwise specified. When referring to the kits separately, this letter will use the term ''household doxycycline hyclate tablet emergency kit'' to refer to the HAK and the term ''individual doxycycline hyclate tablet emergency kit'' to refer to the iHAK.

[3] The term ''eligible'' refers to USPS participants who have agreed in writing to participate in the Postal Module of CRI, have been screened for fitness to receive OSHA-required personal protective equipment, have (including household members) been medically screened for contraindications based on completed health assessment forms, have (including household members) been given a valid prescription, and have (including household members) not otherwise been determined to be ineligible to receive doxycycline hyclate tablet emergency kits.

[4] Your submissions define ''household member'' as ''anyone that considers that address as his or her permanent place of residence.''

[5] Memorandum from Michael Chertoff to Michael O. Leavitt, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (Sept. 23, 2008).

[6] Declaration of Emergency Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b) (Oct. 1, 2008).

[7] The doxycycline hyclate tablet emergency kits for eligible USPS participants and their household members referenced and authorized in this letter fall within the scope of the Secretary of the Department of Health and Human Services' declaration.

[8] Doxycycline hyclate tablets are indicated for treatment of infections caused by ''Anthrax due to *Bacillus anthracis*, including inhalational anthrax (post-exposure): to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis*.'' This indication generally means that drug administration is expected to start after a known or suspected exposure to aerosolized *Bacillus anthracis* spores, but before clinical symptoms of the disease develop. The indication includes presumed exposure, since it is often difficult to know whether and when exposure has actually occurred. The indication also encompasses instances where *Bacillus anthracis* exposure via inhalation is expected and will be imminent. In such cases, the first few doses of prophylaxis may be taken pre-exposure, but the remainder of the course would be taken post-exposure. The indication is commonly referred to as ''post-exposure prophylaxis of inhalational anthrax,'' and this term will be used throughout this letter for ease of reference.

the basis of such determination, the Secretary of the Department of Health and Human Services declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[6,7] Having consulted with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), and having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax for eligible USPS participants and their household members,[8] subject to the terms of this authorization.

The remainder of this letter is organized into four sections: Background, Criteria for Issuance of Authorization, Scope of Authorization, Conditions of Authorization, and Duration of Authorization.

I. Background

CRI involves 72 major metropolitan areas and all 50 states. The primary goal of CRI is to develop the ability to provide mass prophylaxis to 100% of the identified population within 48 hours of notification to do so.

On February 18, 2004, the Secretary of the Department of Health and Human Services (HHS), the Secretary of the Department of Homeland Security (DHS), and the Postmaster General signed a Memorandum of Agreement to explore how the resources of the USPS could be made available to help deliver oral antibiotics in response to a biological terrorism incident. Subsequently, HHS launched CRI and asked the USPS to participate in what has been referred to as the CRI Postal Module (or Postal Plan). The Postal Module involves the delivery of antibiotics to residential households within pre-determined zip codes by USPS participants where there may be an intentional release of *Bacillus anthracis* in their geographic area. The CRI Postal Module could be activated and executed while the municipality is establishing its points-of-dispensing (POD) network for the remainder of the emergency response which, in the case of a wide-area anthrax event, could continue for 1-2 months. The postal carriers' role is voluntary because emergency response is neither part of the basic mission of USPS nor a provision of the contracts between USPS and the unions representing the carriers. USPS has made its participation in the CRI Postal Module contingent on the pre-event provision of prescription antibiotic countermeasures to USPS participants and their household members.

Your request relates to a potential EUA for the pre-event provision and potential use of doxycycline hyclate tablets (100 mg) in the form of emergency kit(s) for eligible USPS participants and their household members. Although doxycycline hyclate tablets are approved for the post-exposure prophylaxis of inhalational anthrax, the emergency kits you describe in your submissions would require an EUA because they would include certain written information that is not currently part of the approved new drug applications (NDAs) or abbreviated new drug applications (ANDAs) for doxycycline hyclate tablets (100 mg). Specifically, you indicated that the following pieces of written information would accompany the doxycycline hyclate tablets:

- Fact Sheet for Recipients
- For the household doxycycline hyclate tablet emergency kit, home preparation instructions for recipients who cannot swallow pills (hereinafter home preparation instructions)
- Information placard (unless the bag is pre-printed with placard information)
- MedWatch Form 3500 for the reporting of any adverse events associated with the doxycycline hyclate tablet emergency kit

In addition, a Fact Sheet for Health Care Providers would be distributed to health care providers and authorized dispensers of the doxycycline hyclate tablet emergency kits.

You propose to use doxycycline hyclate tablets (100 mg) that were manufactured by West-Ward Pharmaceutical Corp., and repackaged by PD-Rx Pharmaceuticals into unit-of-use bottles containing 20 oral tablets each, a 10-day supply.[9]

The doxycycline hyclate tablet emergency kit(s) that are the subject of your request would come in two forms. The first, which you describe as a Household Antibiotic Kit (HAK), would contain a unit-of-use bottle of doxycycline hyclate tablets for each eligible USPS participant and each eligible household member, as well as the Fact Sheet for Recipients, home preparation instructions, MedWatch Form 3500, and information placard (unless bag is pre-printed with placard information) described above. All of these items would be placed in one tamper-evident, clear plastic bag for home storage. The second, which you describe as an individual Household Antibiotic Kit (iHAK), would contain one unit-of-use bottle of doxycycline hyclate tablets for the eligible USPS participant and the Fact Sheet for Recipients, MedWatch Form 3500, and information placard (unless the bag is pre-printed with placard information) described above. All of these items would be placed in a separate tamper-evident, clear plastic bag for secure storage at the USPS participant's workplace, should the USPS participant need to deploy emergently.

II. Criteria for Issuance of Authorization

Having considered the September 23, 2008 determination by the Secretary of the Department of Homeland Security that there is a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents--in this case, *Bacillus anthracis*, and the October 1, 2008 declaration of emergency by the Secretary of Health and Human Services, and having consulted with NIH and CDC, I have concluded that the emergency use of doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax for eligible USPS participants and their household members meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) *Bacillus anthracis* can cause anthrax, a serious or life-threatening disease or condition;

(2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that doxycycline hyclate tablet emergency kits may be effective for post-exposure prophylaxis of inhalational anthrax,[10] and that the known and potential benefits of doxycycline hyclate tablet emergency kits, when used for the post-exposure prophylaxis of inhalational anthrax in the specified population, outweigh the known and potential risks of the product; and

(3) there is no adequate, approved, and available alternative to doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax.[11]

Specifically, I have concluded, pursuant to section 564(c)(1) of the Act, that *Bacillus anthracis* can cause inhalational anthrax, which is a serious or life-threatening disease or condition. The fatality rate for inhalational anthrax in the United States is estimated to be approximately 45 percent to 90 percent. From 1900 to October 2001, there were 18 identified cases of inhalational anthrax in the United States, the latest of which was reported in 1976, with an 89 percent (16/18) mortality rate. Most of these exposures occurred in industrial settings, i.e., textile mills. From October 4, 2001, to December 5, 2001, a total of 11 cases of inhalational anthrax linked to intentional dissemination of *Bacillus anthracis* spores were identified in the United States. Five of these cases were fatal. These fatalities occurred despite aggressive medical care, including treatment with antimicrobial drugs.

I have also concluded that, based on the totality of the scientific evidence available to FDA, including data supporting the safe and effective use of doxycycline hyclate tablets (100 mg) for the post-exposure prophylaxis of inhalational anthrax, the results of CDC's home MedKit study, and information associated with the development of the home preparation instructions, it is reasonable to believe that doxycycline hyclate tablet emergency kits may be effective for the post-exposure prophylaxis of inhalational anthrax pursuant to section 564(c)(2)(A) of the Act.

The above conclusion is largely based on the fact that FDA has previously approved a number of NDAs and ANDAs for doxycycline hyclate tablets for the treatment and post-exposure prophylaxis of inhalational anthrax, as summarized below.

In November 2001, as part of a public health response to the use of anthrax spores

[9] We note that the full course of doxycycline hyclate tablets for adults for the post-exposure prophylaxis of inhalational anthrax is 100 mg twice daily for 60 days. The corresponding oral dosing regimen for children under 100 pounds is 1 mg per pound of body weight twice daily for 60 days.

[10] The Act uses the terms ''diagnosing, treating, or preventing'' in Section 564(c)(2)(A). Post-exposure prophylaxis is encompassed by these statutory terms.

[11] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

as a bioterrorism agent, the Agency published a notice in the *Federal Register* that clarified the dosing recommendations for, among others, doxycycline hyclate products, in the management of patients with inhalational anthrax who had been exposed to spores of *Bacillus anthracis*, but who did not manifest clinical disease.[12] In that notice, FDA announced that it had determined that the language in the labeling of certain drug products, including those containing doxycycline hyclate, is intended to, and does, cover all forms of anthrax, including inhalational anthrax (post-exposure): to reduce the incidence or progression of disease exposure to aerosolized *B. anthracis*. FDA also announced that the appropriate dosing regimen for adults is 100 mg of doxycycline, taken orally twice daily for 60 days; and the corresponding oral dosing regimen for children under 100 pounds is 1 mg per pound (1 mg/lb) of body weight (2.2 mg/kilogram (kg)), given twice daily for 60 days.[13] FDA based these conclusions on the following:

- Effectiveness was supported by minimal inhibitory concentration (MIC) data for the tetracycline class and *Bacillus anthracis*, pharmacokinetic data, data from the Sverdlovsk incident, and the outcome data from a study of inhalational exposure to *Bacillus anthracis* in rhesus monkeys.
- With respect to safety, FDA noted that doxycycline drug products have been used for over 30 years and the literature on the products is voluminous. FDA previously reviewed the literature dealing with the long-term administration of doxycycline for treatment of diseases other than anthrax. Several articles reported the results of studies involving the administration of doxycycline in amounts comparable to the recommended doses. They also involved administration of doxycycline for 60 days and periods approaching and exceeding 60 days. FDA also reviewed data from the Adverse Event Reporting System (AERS). Analysis of these articles and data indicated no pattern of unlabeled adverse events associated with the long-term use of doxycycline.
- FDA also noted that doxycycline and other members of the tetracycline class of antibiotics are not generally indicated for the treatment of any patients under the age of 8 years. Tetracyclines are known to be associated with teeth discoloration and enamel hypoplasia in children and delays in bone development in premature infants after prolonged use. FDA balanced the nature of the effect on teeth and the fact that this delay in bone development is apparently reversible against the lethality of inhalational anthrax, and concluded that doxycycline drug products can be labeled with a pediatric dosing regimen for inhalational anthrax (post-exposure).

As noted above, FDA has approved, under section 505(j) of the Act, a number of abbreviated new drug applications (ANDAs), including West-Ward's ANDA (#65-095) for doxycycline hyclate tablets (100 mg) for treatment and post-exposure prophylaxis of inhalational anthrax on July 2, 2003. West-Ward's doxycycline hyclate tablets (100 mg), which have been repackaged and re-labeled by PD-Rx Pharmaceuticals, are the subject of this emergency use authorization. This product is the same as the reference listed drug, Vibra-Tabs (doxycycline hyclate tablets, 100 mg; NDA #50-333), within the meaning of section 505(j) of the Act.

I have also considered CDC's home MedKit study and information associated with the development of the home preparation instructions as part of the totality of the scientific evidence available to FDA, and have determined that this information helps to support the conclusion that it is reasonable to believe that doxycycline hyclate tablet emergency kits may be effective for post-exposure prophylaxis of inhalational anthrax, as summarized below.

The CDC study evaluated the ability of study participants to receive what was referred to as a MedKit -- doxycycline[14] with certain written information, including emergency use instructions and home preparation instructions similar to those being authorized here. A convenience sample of 4,250 St. Louis area households, divided among three cohorts, was enrolled in the study after medical screening and informed consent. The primary outcomes for this evaluation were to determine the extent to which participants would follow instructions for appropriately keeping the MedKits intact and reserving them for emergency use until directed by a local government official. Although this study had a number of limitations as explained below, approximately 97% of all study respondents returned the MedKits upon completion of the study.

Finally, FDA considered information associated with the development of the home preparation instructions for doxycycline hyclate tablets. FDA had previously developed home preparation instructions and these instructions were tested by the Chicago Department of Public Health, which provided its results to FDA. The Agency revised the home preparation instructions based on these findings and performed additional laboratory tests and limited palatability testing. FDA also worked with CDC to improve the readability of the instructions.

Although FDA has approved a number of NDAs and ANDAs for doxycycline hyclate tablets (100 mg) for the treatment and post-exposure prophylaxis of inhalational anthrax, these products are not approved with emergency use instructions and home preparation instructions. The amount and nature of the scientific evidence regarding the ability to use emergency use instructions and home preparation instructions is more limited than the scientific evidence supporting the approval of doxycycline hyclate tablets for the post-exposure prophylaxis of inhalational anthrax. However, taking into consideration the potentially fatal nature of anthrax disease, the CDC home MedKit study and the information associated with the development of the home preparation instructions also helps to support a conclusion that it is reasonable to believe that doxycycline hyclate tablet emergency kits may be effective for the post-exposure prophylaxis of inhalational anthrax. Accordingly, based on the totality of the scientific evidence available to FDA, it is reasonable to believe that doxycycline hyclate tablet emergency kits may be effective for the post-exposure prophylaxis of inhalational anthrax.

I have also concluded, pursuant to section 564(c)(2)(B) of the Act, that it is reasonable to believe that the known and potential benefits of doxycycline hyclate tablet emergency kits outweigh the known and potential risks of the product for USPS participants and their household members. The available scientific evidence that supports this conclusion is summarized below.

We have already concluded, as evidenced by the previous NDA and ANDA approvals discussed above, that the known and potential benefits of the approved doxycycline hyclate tablets (100 mg) for post-exposure prophylaxis of inhalational anthrax outweigh the known and potential risks of the product. Under this EUA, doxycycline hyclate tablets will be packaged with additional written information (including emergency use instructions and home preparation instructions) that has not been approved by FDA as part of a new drug application. CDC's home MedKit study and the process by which home preparation instructions were developed, as discussed above, help to further inform the requisite risk-benefit analysis under section 564(c)(2)(B).

The CDC home MedKit study was somewhat limited in its ability to address certain questions about home storage and use since the participants were not required to follow any directions for preparation or use of doxycycline hyclate tablets in an actual emergency. The effect of the actual storage conditions on the stored drug product was not tested and the instructions for storage did not provide the temperature conditions for storage on the outside of the bag. Despite the limitations of the CDC home MedKit study, it is important to note that approximately 97% of all study respondents returned the MedKits upon completion of the study.

As described above, the development of the home preparation instructions has been informed by limited testing and input from CDC. However, the current version of the home preparation instructions has not been subjected to formal independent testing procedures for an assessment of an individual's understanding or his/her ability to follow the directions.

Because of the limitations of the CDC study and the lack of formal independent testing on the home preparation instructions, FDA cannot conclude without further testing and

[12] *See* 66 Fed. Reg. 55679 (Nov. 2, 2001); Docket 01N-0494.

[13] *Id.* The *Federal Register* notice further requested that applicants for these products submit labeling supplements to update their package inserts with this information.

[14] In this study, participants who were allergic to doxycycline or for whom doxycycline was otherwise contraindicated received ciprofloxacin.

information that the emergency use instructions and home preparation instructions pose no additional risks to eligible USPS participants and their household members. Inappropriate use and the development of doxycycline resistant microorganisms could be a potential issue if a considerable number of eligible USPS participants take the product for an unintended purpose.

The known and potential risks of eligible USPS participants and their household members not being able to store, prepare, and use doxycycline hyclate tablets in accordance with the emergency use instructions and home preparation instructions, and of experiencing adverse reactions, is outweighed by the known and potential benefits of using doxycycline hyclate tablets as a safe and effective treatment against an otherwise potentially fatal aerosolized anthrax attack. For the foregoing reasons, it is reasonable to believe that the known and potential benefits of the doxycycline hyclate tablet emergency kits (including emergency instructions and home preparation instructions as authorized) for the post-exposure prophylaxis of inhalational anthrax in the specified population outweigh the known and potential risks of the product under the terms of this letter of authorization.[15]

I have also concluded, pursuant to section 564(c)(3) of the Act, that there is no adequate, approved, and available alternative to the doxycycline hyclate tablet emergency kits for post-exposure prophylaxis of inhalational anthrax in the specified population. Although doxycycline hyclate is approved for treatment and post-exposure prophylaxis of inhalational anthrax, the emergency use instructions and home preparation instructions included here as part of the doxycycline hyclate tablet emergency kits are not approved by FDA.

Other products approved for treatment and post-exposure prophylaxis of inhalational anthrax include penicillin G procaine, ciprofloxacin, and levofloxacin. However, none of these products is approved with emergency use instructions. In addition, penicillin G procaine is administered by injection and fluoroquinolones (ciprofloxacin and levofloxacin) have additional significant adverse events reported following their use, including adverse tendon effects and rupture, peripheral neuropathy, and central nervous system disorders.

Further, Biothrax (Anthrax Vaccine Adsorbed) is indicated for the active immunization against *Bacillus anthracis* of individuals between 18 and 65 years of age who come in contact with animal products such as hides, hair or bones that come from anthrax endemic areas, and that may be contaminated with *Bacillus anthracis* spores. This product is not considered an ''adequate, approved, and available'' alternative for several reasons including: (1) the license for Biothrax does not extend to post exposure use; (2) the immunization consists of three subcutaneous injections given 2 weeks apart followed by three additional subcutaneous injections given at 6, 12 and 18 months; and (3) following the initial injections, time is needed to develop the antibodies. Therefore, I have concluded that there is no adequate, approved, and available alternative to doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax for the specified population.

III. Scope of Authorization

Pursuant to section 564(d)(1) of the Act, this authorization is limited to the use of doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax[16] for eligible[17] USPS participants in the Postal Module of CRI and their household members.

The doxycycline hyclate tablets authorized under this EUA were manufactured by West-Ward Pharmaceutical Corp. and have been repackaged into unit-of-use bottles containing 20 tablets (a 10-day supply) by PD-Rx Pharmaceuticals, consistent with current Good Manufacturing Practice (CGMP) and the Draft Guidance entitled ''Expiration Dating of Unit-Dose Repackaged Drugs; Compliance Policy Guide.'' The product has been stored under conditions consistent with the manufacturer's labeled storage conditions and CGMP and is within its labeled expiration date. Once doxycycline hyclate tablets covered by this EUA have passed their expiration date, they are outside the scope of this EUA.

ASPR will determine whether to initiate distribution of product under this EUA to particular CRI locations based on:

(a) whether the municipality has submitted a Strategic Security Plan acceptable to USPS and ASPR;

(b) whether the municipality, in collaboration with pertinent State public health officials, local law enforcement agencies, USPS, ASPR, and other appropriate entities, has developed a mutually acceptable set of policies and procedures for recruiting USPS participants, screening them for fitness to receive doxycycline hyclate tablets, providing the doxycycline hyclate tablet emergency kits to eligible USPS participants and their household members, and maintaining the readiness of the participant force. Policies and procedures must also include screening for fitness to receive OSHA-required personal protective equipment (PPE) (i.e., N95 masks) and provision of PPE to eligible USPS participants;[18]

(c) whether ASPR has determined that it has sufficient funds to cover the costs of CRI Postal Module implementation in that location.

After the distribution decision has been made by ASPR and conveyed to FDA, the unit-of-use bottles will be delivered to secure site(s), where the participating public health authority(ies) will assume control over them. Under this EUA, the unit-of-use bottles will be repackaged and relabeled[19] into doxycycline hyclate tablet emergency kits by licensed health care providers under the auspices of the participating public health authority(ies).

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the doxycycline hyclate tablet emergency kits, when used for the post-exposure prophylaxis of inhalational anthrax, outweigh the known and potential risks of the product for the population described above.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the doxycycline hyclate tablet emergency kits may be effective for the post-exposure prophylaxis of inhalational anthrax pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available, including the information described in Section II above, and concludes that the doxycycline hyclate tablet emergency kits, when used for the post-exposure prophylaxis of inhalational anthrax in the specified population, meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The pre-event distribution and use of doxycycline hyclate tablet emergency kits under this EUA must conform to and may not exceed the terms of this letter of authorization, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of Homeland Security's determination under section 564(b)(1)(A) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), doxycycline hyclate tablet emergency kits are authorized for the post-exposure prophylaxis of inhalational anthrax for eligible USPS participants and their household members.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act. When the EUA ceases to be effective, doxycycline hyclate tablet emergency kits will no longer be authorized for emergency use under this EUA, and doxycycline hyclate tablet emergency kits that have been distributed under this EUA must be collected as described in this letter of authorization.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

A. BARDA will provide to the participating public health authority(ies) the written materials included in BARDA's October 3, 2008 submission, as amended on February 19, 2009, and authorized under this EUA.

B. The participating public health authority(ies) will conduct an educational and information program under appropriate

[15] The terms of this letter of authorization, including its scope and conditions, are integral to the conclusions regarding the known and potential risks and benefits of the emergency use of this product in eligible USPS participants and their household members.

[16] See footnote 8.

[17] See footnote 3.

[18] The emergency use of unapproved, unlicensed, or uncleared PPE or the unapproved use of approved, licensed, or cleared PPE is not authorized as part of this EUA.

[19] The term ''repackaged and relabeled'' will be used to refer to the activity of putting unit-of-use bottles into clear, tamper-evident bags with the addition of certain written information.

conditions designed to ensure that health care providers or other authorized dispensers (hereinafter health care providers) distributing doxycycline hyclate tablet emergency kits are informed:

(1) that FDA has authorized the emergency use of doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax for eligible USPS participants and their household members;

(2) of the significant known and potential benefits and risks of the emergency use of doxycycline hyclate tablet emergency kits, and of the extent to which such benefits and risks are unknown for eligible USPS participants and their household members; and

(3) of the alternatives to doxycycline hyclate tablet emergency kits for eligible USPS participants and their household members, and of their benefits and risks.

With respect to condition (2) above, relating to provision of the significant known and potential benefits and risks of the emergency use of doxycycline hyclate tablet emergency kits, the participating public health authority(ies) will ensure that the manufacturer's package insert is provided to all health care providers who distribute doxycycline hyclate tablet emergency kits to eligible USPS participants and their household members. With respect to conditions (1) - (3), the participating public health authority(ies) will ensure that health care providers are provided with the authorized Fact Sheet for Health Care Providers. Any revision to the authorized Fact Sheet for Health Care Providers is subject to FDA's prior approval. The participating public health authority(ies) will also ensure that all such health care providers are provided with the same information as that provided to eligible recipients described immediately below.

C. The participating public health authority(ies) will conduct an educational and information program under appropriate conditions designed to ensure that individuals to whom doxycycline hyclate tablet emergency kits are distributed are informed:

(1) that FDA has authorized the emergency use of doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax for eligible USPS participants and their household members;

(2) of the significant known and potential benefits and risks of the emergency use of doxycycline hyclate tablet emergency kits for eligible USPS participants and their household members, and of the extent to which such benefits and risks are unknown; and

(3) of the option to accept or refuse administration of doxycycline hyclate tablet emergency kits, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available, and of their benefits and risks.

As a condition of this authorization, the participating public health authority(ies) will ensure that, prior to distribution of doxycycline hyclate tablet emergency kits, the authorized information that meets the requirements set forth above is provided to each eligible recipient (i.e., in the case of the **household** doxycycline hyclate emergency kit, the Fact Sheet for Recipients, home preparation instructions, and information placard (or bag pre-printed with placard information); in the case of the **individual** doxycycline hyclate emergency kit, the Fact Sheet for Recipients, and information placard (or bag pre-printed with placard information)). Any revision to the authorized information for potential recipients is subject to FDA's prior approval.

D. The participating public health authority(ies) will distribute doxycycline hyclate tablet emergency kits to eligible recipients through health care providers who are qualified and licensed under applicable state law to dispense prescription drugs. The health care providers will distribute doxycycline hyclate tablet emergency kits under conditions that assure that otherwise eligible[20] recipients are screened for medical eligibility (including contraindications) and are issued prescriptions for the doxycycline hyclate tablet emergency kit. Such conditions shall include exclusion of a USPS participant if:

- No medical history and Health Assessment Form is available for the USPS participant or any member of their household; or
- Doxycycline hyclate is contraindicated for the USPS participant.

The participating public health authority(ies) must ensure documentation of eligibility or ineligibility to receive doxycycline hyclate tablet emergency kits. If doxycycline hyclate tablets are contraindicated for any of the USPS participant's household members, the USPS participant can still receive the doxycycline hyclate tablet emergency kit if s/he consents in writing to accept an incomplete kit and acknowledges that the household member(s) will have the same dependence on whatever community-based mass prophylaxis is available to the general public in an emergency.

USPS will be responsible for providing copies of the authorized Health Assessment Form to potential USPS participants. If they elect to apply for participation, potential USPS participants and their household members should complete Health Assessment Forms and mail them to the participating public health authority(ies) at the address provided. Qualified health care providers, under the auspices of the participating public health authority(ies), will be responsible for reviewing the completed Health Assessment Forms to determine whether potential recipients are eligible to receive doxycycline hyclate tablet emergency kits prior to dispensing such kits to eligible USPS recipients . Any revision of the authorized Health Assessment Form is subject to FDA's prior approval. A health care provider will review with each USPS participant his/her Health Assessment Form and the Health Assessment Form corresponding to each family member and will comply with applicable state prescribing laws before authorizing the filling of one unit-of-use bottle for each eligible USPS participant and household member. See Section D below for requirements regarding repackaging and relabeling of doxycycline hyclate tablet emergency kits prior to dispensing to eligible recipients.

E. Doxycycline hyclate tablet emergency kits must be manufactured, (re)packaged, (re)labeled, and held according to applicable good manufacturing practice requirements, except that with respect to the doxycycline hyclate tablet emergency kits that will be repackaged and relabeled by participating local public health authorities using the doxycycline unit-of-use bottles manufactured by West-Ward Pharmaceutical Corp. and repackaged by PD-Rx Pharmaceuticals described in this EUA, the Secretary waives good manufacturing practice requirements applicable to the repackaging and relabeling of such kits, subject to the following requirements

- The participating public health authority(ies) will be responsible for repackaging and relabeling doxycycline hyclate unit-of-use bottles into doxycycline hyclate tablet emergency kits through health care providers qualified and licensed under state law to dispense prescription drugs.
- The packaging and relabeling described below should be performed in a controlled environment such that there is adequate space, lighting, and freedom from debris and from other drug products to prevent mix-ups or cross-contamination.

- A health care provider who initially assembles the doxycycline hyclate tablet emergency kits will do the following:
  - The health care provider will determine the number of authorized individuals in a household eligible to receive the product using the completed Health Assessment Form. The health care provider will document the prescription number, lot number, and expiration date of doxycycline hyclate for each authorized individual.
  - The health care provider will record all prescription numbers for the household on the Healthcare Provider Quality Checklist.
  - The health care provider will be responsible for maintaining an inventory/drug accountability record. At a minimum, this record will contain a running total/balance, the date filled, household name, and number of unit-of-use bottles dispensed to a household. The prescription number, lot number, and expiration date of the doxycycline hyclate tablets for each authorized individual will also be recorded.
  - For the **household** doxycycline hyclate tablet emergency kit, the health care provider will place the correct number of unit-of-use bottles of doxycycline hyclate (corresponding to the authorized USPS participant and each authorized

[20] USPS postal carriers are not eligible to receive a doxycycline hyclate tablet emergency kit if they have not passed their N95 mask fit test. See Section III, Scope of Authorization, above.

household member) in one clear, tamper-evident plastic bag. Each unit-of-use bottle will be labeled with the appropriate authorized individual's name.

- For an **individual** doxycycline hyclate tablet emergency kit, the health care provider will place one unit-of-use bottle of doxycycline hyclate tablets in a separate clear, tamper-evident plastic bag for the authorized USPS participant for secure storage by the USPS at work. The unit-of-use bottle will be labeled with the authorized USPS participant's name.
- For the **household** doxycycline hyclate tablet emergency kit, the health care provider will place the Fact Sheet for Recipients, home preparation instructions, and MedWatch Form 3500 inside and in the outer pocket of the clear, tamper-evident plastic bag; and, if the bag is not pre-printed with placard information, the health care provider will place the information placard inside the bag facing out so the wording is plainly visible.
- For the **individual** doxycycline hyclate tablet emergency kit, the health care provider will place the Fact Sheet for Recipients and MedWatch Form 3500 Form inside and in the outer pocket of the clear, tamper-evident plastic bag; and, if the bag is not pre-printed with placard information, the health care provider will place the information placard inside the bag facing out so the wording is plainly visible.
- The health care provider will complete the first page of the Healthcare Provider Quality Checklist, including signature and date.
- The health care provider will **not** seal the bag, and will give it to the identified health care provider to check the contents of the bags as described below.
- Before dispensing, a different health care provider will check each doxycycline hyclate tablet emergency kit that has been assembled as follows:
- Review and verify Health Assessment Forms for eligibility of USPS participant and each household member to receive the doxycycline hyclate tablet emergency kit.
- Verify that each unit-of-use bottle is labeled with the authorized individual's name.
- Verify the prescription number, lot number, and expiration date of the doxycycline hyclate tablets for each authorized individual on the Health Assessment Forms.
- Verify prescription numbers for each authorized individual on the Healthcare Provider Quality Checklist.
- For the **household** doxycycline hyclate tablet emergency kit, verify that the correct number of unit-of-use bottles of doxycycline hyclate tablets have been placed in the tamper-evident bag for that household based on the number of household members eligible. For the **individual** doxycycline hyclate tablet emergency kit, verify that the correct unit-of-use bottle of doxycycline hyclate tablets has been placed in the tamper-evident bag for the USPS participant for secure storage by USPS at work.
- Verify that the appropriate written information is inside the tamper-evident bags.
- Verify that the appropriate written information is in the outer pocket of the tamper-evident bags.
- If the information placard is not pre-printed on the outside of the tamper-evident bags, verify that the information placard is inside the tamper-evident bags and plainly visible.
- Complete the second page of the Healthcare Provider Quality Checklist, including signature and date.
- Seal the bags.
- Attach the Healthcare Provider Quality Checklist to the Health Assessment Forms for the household.
- The doxycycline hyclate tablet emergency kits may then be dispensed to the USPS participant along with review of the instructions and information.

The authorized Healthcare Provider Quality Checklist and placard information will be used. Any revision of the authorized Healthcare Provider Quality Checklist or placard information is subject to FDA's prior approval.

F. ASPR will record the amount of unit-of-use bottles of doxycycline hyclate tablets (including lot numbers) shipped under this EUA to the participating public health authority(ies) for use by eligible USPS participants and their households. Such records will be made available to FDA for inspection upon request. However, the the participating public health authority(ies) responsible for distributing the doxycycline hyclate tablet emergency kits will prepare, maintain, and make available records and provide reports as directed by ASPR/FDA.

G. Once an **individual** doxycycline hyclate tablet emergency kit has been dispensed to an eligible USPS participant, USPS will store the **individual** doxycycline hyclate tablet emergency kit in a secure location for the eligible USPS participant.

H. ASPR, USPS, and the participating public health authority(ies) may only provide written materials as included in BARDA's October 3, 2008 submission, as amended on February 19, 2009, and authorized under this EUA. Any revisions or additional written materials to be provided by ASPR, USPS, or the participating public health authority(ies) are subject to FDA's prior approval, except that USPS may provide additional materials for recruitment purposes to the extent that those materials are consistent with the materials included in BARDA's October 3, 2008 submission, as amended on February 19, 2009, that are authorized under this EUA. The participating public health authority(ies) may evaluate activities undertaken pursuant to this authorization. To ensure consistency with this authorization, the participating public health authority(ies) must consult with FDA before conducting such evaluations.

I. The participating public health authority(ies) will conduct an adverse event monitoring and reporting program designed to ensure that adverse events and medication errors associated with the use of the doxycycline hyclate tablet emergency kit are documented and reported within 15 days to MedWatch through *www.fda.gov/medwatch*, by submitting MedWatch Form 3500 in hard copy, or by calling 1-800-FDA-1088; and that any such report identifies the product as ''doxycycline hyclate tablet emergency kit'' and includes in the description of the event the designation ''USPS-CRI EUA'' or ''USPS-CRI Emergency Use Authorization.'' As part of this program, health care providers will be provided copies of MedWatch Form 3500, recipients will be instructed to report if they take any of the doxycycline hyclate tablets in their emergency kit and experience an adverse event or medication error, MedWatch Form 3500 will be included in each doxycycline hyclate tablet emergency kit, and recipients will be provided with a toll-free number for contacting a health care provider if they experience an adverse event or medication error. The participating public health authority(ies) will maintain associated records until notified by FDA and will make such records available to FDA for inspection upon request.

J. The participating public health authority(ies) will periodically verify and document that any undistributed doxycycline hyclate is within its labeled expiration date. The participating public health authority(ies) will maintain any associated records until notified by FDA and will make such records available to FDA for inspection upon request. Appropriate local public health authorities will periodically verify and reconcile drug accountability records.

K. USPS will be responsible for providing USPS participants every six months with the Form entitled ''Questions to Determine Status of Your Household Antibiotic Kit (HAK)'' (Kit Status form) to document whether (a) they have stored their kits as instructed; (b) they are able to locate their kits readily; (c) their kits are intact; and (d) the doxycycline hyclate in their kits has not expired. USPS participants should complete these forms and mail them to the participating public health authority(ies) at the address provided. The participating public health authority(ies) will ascertain the circumstances surrounding non-compliance for USPS participants who (a) report loss of a kit; (b) report use of doxycycline hyclate from the emergency kit in the absence of instructions to do so; or (c) fail to return a completed Kit Status Form. Depending on its findings, the participating public health authority(ies) may disqualify an individual from further participation. If the doxycycline hyclate emergency kit will expire before the next 6-month follow-up, a new doxycycline hyclate emergency kit will be prescribed for eligible participants in accordance with paragraph D and the other terms of this letter. In such cases, USPS will be responsible for collecting such kits and turning them over to the participating public health authority(ies), which then will be responsible for accounting for them and disposing ofthem as instructed by ASPR. The participating public health authority(ies) will maintain drug accountability records. The participating public health authority(ies) will also

ascertain whether there have been any adverse events or medication errors associated with the doxycycline hyclate tablet emergency kit. If any such adverse events or medication errors have not previously been reported to FDA as outlined in paragraph H, they must be reported within 15 days to FDA. FDA has authorized ASPR's Form entitled ''Questions to Determine Status of Your Household Antibiotic Kit (HAK)'' (Kit Status form). Any revision of the Kit Status form is subject to FDA's prior approval. USPS, in conjunction with appropriate local public health authorities, will be responsible for ensuring that completed Kit Status forms are maintained until notified by FDA. A report summarizing the information collected on Kit Status forms under this paragraph will be submitted to FDA within 30 days of gathering such information. Associated records will be made available to FDA for inspection upon request.

L. USPS will be responsible for collecting any expired doxycycline hyclate tablet emergency kits and turning them over to the participating public health authority(ies). The participating public health authority(ies) will be responsible for disposing of expired doxycycline hyclate tablet emergency kits as instructed by ASPR at that time. The participating public health authority(ies) will ensure that drug accountability records are maintained and reconciled. Such records shall be made available to FDA for inspection upon request.

M. USPS and the participating public health authority(ies) will be responsible for ensuring that completed Health Assessment Forms, Healthcare Provider Quality Checklists, and any other records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

N. As a condition of this EUA, all advertising and promotional descriptive printed matter relating to the use of doxycycline hyclate tablet emergency kits authorized under this EUA shall be consistent with the Fact Sheets, home preparation instructions, and placard information, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

O. Upon termination of the declaration of emergency under section 564(b)(2) of the Act or upon revocation of this EUA under section 564(g) of the Act, USPS will be responsible for collecting all doxycycline hyclate tablet emergency kits and turning them over to the participating public health authority(ies). The participating public health authority(ies) will dispose of doxycycline hyclate emergency kits as instructed by ASPR at that time. The participating public health authority(ies) will ensure that drug accountability records are maintained and reconciled. Such records will be made available to FDA for inspection upon request.

P. HHS will notify FDA of its decision to add a CRI location and its decision to initiate distribution of doxycycline hyclate tablet emergency kits under this EUA to particular CRI locations.

The emergency use of doxycycline hyclate tablet emergency kits as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

Dated: June 17, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–15044 Filed 6–25–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2896–FN2]

Medicare and Medicaid Programs; Approval of the Joint Commission's Continued Deeming Authority for Critical Access Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final Notice of Removal of Conditional Probationary Status.

SUMMARY: Based on our review and observations, we have determined that the Joint Commission's accreditation standards for critical access hospitals (CAHs) meet or exceed our requirements. Therefore, this final notice announces our decision to approve without condition the Joint Commission's request for continued recognition as a national accreditation program for CAHs seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice of approval is effective November 21, 2008 through November 21, 2011.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310. Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a Critical Access Hospital (CAH) provided certain requirements are met. Sections 1820(c)(2)(B) and 1861(mm) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. Under this authority, the minimum requirements that a CAH must meet to participate in Medicare are set forth in regulations at 42 CFR part 485, subpart F (Conditions of Participation: Critical Access Hospitals (CAHs)) which determine the basis and scope of CAH covered services. Conditions for Medicare payment for CAHs are set forth at § 413.70. Applicable regulations concerning provider agreements are located in 42 CFR part 489 (Provider Agreements and Supplier Approval) and those pertaining to facility survey and certification are located in 42 CFR part 488, subparts A and B.

In general, we approve a CAH for participation in the Medicare program if it is participating as a hospital at the time it applies for CAH designation, and it is in compliance with part 482 (Conditions of Participation for Hospitals) and part 485, subpart F (*Conditions of Participation:* Critical Access Hospital (CAHs)).

For a CAH to enter into a provider agreement, a State survey agency must certify that the CAH is in compliance with the conditions or standards set forth in section 1820 of the Act and part 485 of our regulations. Thereafter, the CAH is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. There is, however, an alternative to State compliance surveys. Accreditation by a nationally-recognized accreditation program can substitute for ongoing State review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization (AO) that all applicable Medicare conditions are met or exceeded, we may ''deem'' that provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

A national AO applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions of participation. Our regulations concerning re-approval of AOs are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require AOs to reapply for continued approval of deeming authority every 6 years, or sooner as we determine. The regulations at § 488.8(f)(3)(i) provide CMS the authority to grant conditional approval of an AO's deeming authority, with a 180-day probationary period, if the AO has not adopted comparable standards during the reapplication process.

We received a complete application from the Joint Commission for continued recognition as a national accrediting organization for CAHs on March 28, 2008. In accordance with the