grants, governed by two separate Program Instructions (PIs). The training and data grants are governed by the ''new grant'' PI and the basic grant is governed by the ''basic grant'' PI. Current PIs require separate applications and program assessment reports for each grant. Every State applies for at least two of the grants annually and most States apply for all three. As many of the application requirements are the same for all three grants, this results in duplicative work and high degrees of repetition for State courts applying for more than one CIP grant.

The purpose of this Program Instruction is to streamline and simplify the application and reporting processes by consolidating the PIs into one single PI and requiring one single, consolidated application (App) package and program assessment report (PAR) per State court annually. These revisions will satisfy statutory programmatic requirements and reduce both the number of required responses and associated total burden hours for State courts.

This new PI also describes programmatic and fiscal provisions and reporting requirements for the grants, specifies the application submittal and approval procedures for the grants for fiscal years 2012 through 2015, and identifies technical resources for use by State courts during the course of the grants. The agency uses the information received to ensure compliance with the statute and provide training and technical assistance to the grantees.

Respondents: Highest State Courts of Appeal

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
App	52	1	92	4784
PAR	52	1	86	4472

Estimated Total Annual Burden Hours: 9,256.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *Email address: infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* (202) 395–7285, *Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–30553 Filed 11–25–11; 8:45 am]

BILLING CODE 4184–01–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 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 United States Postal Service (USPS) participants in the Cities Readiness Initiative (CRI) and their household members issued on October 3, 2008, as amended on February 25, 2009, and on August 23, 2010, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by the Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS). Following issuance of FDA's August 23, 2010, amended Authorization letter, on April 8, 2011, BARDA submitted a request on behalf of ASPR to further amend the Authorization to reflect certain programmatic changes, including by replacing references to the CRI with the National Postal Model (NPM). In response to BARDA's request, FDA amended the Authorization letter and reissued the Authorization in its entirety on October 14, 2011. The Authorization, as amended and reissued, includes explanations for its reissuance and is reprinted in this document.

DATES: The amended Authorization is effective as of October 14, 2011.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4121, Silver Spring, MD 20993. 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: Luciana Borio, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4280, Silver Spring, MD 20993–0002, (301) 796–4637.

SUPPLEMENTARY INFORMATION:

I. Amendment to the October 3, 2008, Authorization for Doxycyline Hyclate Tablet Emergency Kits, as Amended

In 2004, the Secretary of the Department of Homeland Security (DHS) issued a material threat determination indicating that *Bacillus anthracis* (*B. anthracis*), the biological agent that causes anthrax disease, presents a material threat against the

population of the United States sufficient to affect national security. On September 23, 2008, under section 564(b)(1)(A) of the FD&C Act (21 U.S.C. 360bbb–3(b)(1)(A)), as amended by the Project BioShield Act of 2004 (Pub. L. 108–276), the Secretary of DHS determined that there is a significant potential for a domestic emergency involving a heightened risk of attack with a specific biological, chemical, radiological, or nuclear agent or agents—in this case, *B. anthracis.* On October 1, 2008, under section 564(b) of the FD&C Act, and on the basis of such determination, the Secretary of HHS then 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 section 564(a) of the FD&C Act, and on October 1, 2009, and on October 1, 2010, renewed the declaration. On July 20, 2011, the Secretary of HHS renewed and amended the declaration to apply to all oral formulations of doxycycline, including doxycycline hyclate tablets covered by the Authorization, accompanied by emergency use information subject to the terms of any authorization issued under section 564(a) of the FD&C Act. Notice of the declaration of the Secretary was published in the **Federal Register** of July 27, 2011 (76 FR 44926).

On October 1, 2008, BARDA requested and on October 3, 2008, FDA issued an EUA for doxycycline hyclate tablet emergency kits for eligible USPS participants in the CRI and their household members, subject to the terms and conditions of the Authorization. As required under section 564(h)(1) of the FD&C Act, in the **Federal Register** of October 21, 2008 (73 FR 62507), FDA published the Authorization for doxycycline tablet emergency kits for eligible USPS participants in the CRI and their household members, including an explanation of the reasons for its issuance. 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 tablet emergency kits and to clarify 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. In the **Federal Register** of June 26, 2009 (74 FR 30577), FDA published the amended Authorization, including an explanation of the reasons for the amendment. On August 4, 2010, BARDA requested that the EUA be further amended to permit the use of a certain manufacturer and a certain repackager under the EUA. On August 23, 2010, in response to BARDA's request, FDA amended the Authorization letter and reissued the Authorization letter in its entirety. On April 8, 2011, BARDA requested that the EUA be further amended to reflect programmatic and operational changes, including by replacing references to the CRI with the NPM, clarifying roles and responsibilities, and revising or removing certain written materials provided for in the Authorization. On October 14, 2011, 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 document and the full text of the Authorization are available on the Internet at *http://www.regulations.gov.*

III. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C 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 subject to the terms and conditions of the Authorization. The letter of Authorization in its entirety (not including the amended authorized versions of the fact sheets and other written materials), as amended on February 25, 2009, on August 23, 2010, and on October 14, 2011, follows and provides an explanation of the reasons for its amendment.

Dated: November 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

October 14, 2011

Nicole Lurie, M.D., M.S.P.H.
Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Lurie:

This letter is in response to the Biomedical Advanced Research and Development Authority's (BARDA) October 1, 2008, submission, as amended,[1] requesting that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of doxycycline hyclate tablets contained in individual or household antibacterial drug kits for the post-exposure prophylaxis[2] of inhalational anthrax during a public health emergency involving aerosolized *Bacillus anthracis* (*B. anthracis*), pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. § 360bbb-3). BARDA's request is specifically for doxycycline hyclate tablet emergency kits for eligible United States Postal Service (USPS) employee volunteers who are participating in the National Postal Model (NPM) (hereinafter USPS participants) and their household members. For the purpose of this letter, "emergency use of doxycycline hyclate tablet emergency kits" includes NPM pre-event preparedness activities for, and post-event implementation of, post-exposure prophylaxis of inhalational anthrax with authorized doxycycline hyclate tablet emergency kits for eligible USPS participants and their household members. In submitting this request, ASPR/BARDA, in coordination with USPS, will be responsible for requesting any amendments to the EUA.

In 2004, the Secretary of the Department of Homeland Security (DHS) issued a Material Threat Determination indicating that *B. anthracis*, the biological agent that causes anthrax disease, presents a material threat against the population of the United States sufficient to affect national security. On September 23, 2008, pursuant to section 564(b)(1)(A) of the FD&C Act (21 U.S.C. § 360bbb-3(b)(1)(A)), the Secretary of DHS 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, *B. anthracis*.[3] On October 1, 2008,

[1] Following issuance of FDA's October 3, 2008, authorization letter, BARDA submitted a request on February 19, 2009, to further amend the authorization. On February 25, 2009, an amended authorization letter responding to that request was issued. On August 4, 2010, BARDA requested that the EUA be further amended, and on August 23, 2010, an amended authorization letter responding to that request was issued. On April 8, 2011, BARDA requested that the EUA be further amended to reflect programmatic and operational changes, as described in this authorization letter; to remove references to protective equipment, e.g., N95 masks; and to update or remove certain materials, including removing the unit-of-use bottle label and approved package inserts. This letter grants that request.

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

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

pursuant to section 564(b) of the FD&C Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the HHS Secretary then declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets for post-exposure prophylaxis accompanied by emergency use information subject to the terms of any authorization issued under section 564(a) of the FD&C Act (21 U.S.C. § 360bbb-3(a)), and on October 1, 2009, and on October 1, 2010, renewed that declaration.[4] On July 20, 2011, the Secretary of HHS renewed and amended that declaration so that it applies to all FDA-approved oral formulations of doxycycline products, including doxycycline hyclate tablets covered by this authorization.[5]

Following the 2004 signing of a Memorandum of Agreement by the HHS Secretary, DHS Secretary, and Postmaster General, the Cities Readiness Initiative (CRI) Postal Model (also referred to as the Postal Plan) was launched to augment the dispensing of oral antibacterial drugs through USPS participants' delivery of antibacterial drugs to residential households within pre-determined ZIP Codes where there may be an intentional release of *B.anthracis* in their geographic area. BARDA is requesting an amendment to its October 1, 2008, submission, as amended,[6] to reflect programmatic and operational changes in the Postal Model. Specifically, ASPR seeks to provide doxycycline hyclate tablet emergency kits, where not contraindicated, to eligible USPS employee volunteers who are participating in a venue-specific adaptation of the NPM and to their household members.[7] The program name "NPM" replaces references to "CRI" following Executive Order 13527, which was issued in December 2009 and directed the establishment of a national USPS model for residential delivery of antibacterial drugs following a biological attack.[8] The resulting NPM will guide local planning for venue-specific Postal Plans and is replicable in any United States metropolitan area whose jurisdictions are willing to engage in the local pre-event preparations necessary to establish such a capability. In order to sustain and expand the Postal Model, HHS/ASPR is assuming many of the programmatic and operational responsibilities for the NPM. For purposes of this authorization, ASPR is the responsible HHS entity, regardless of the office, i.e., BARDA, Office of Preparedness and Emergency Operations (OPEO), or the National Disaster Medical System (NDMS), that has been delegated the specific responsibility.

Pre-event preparation will enable USPS participants to participate in the earliest phase of the public health response to an anthrax event by delivering post-exposure prophylaxis on an emergency basis as a quick strike force directly to residences throughout an at-risk geographic area(s). 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 Postal Model contingent on the pre-event provision of prescription antibacterial drug countermeasures to USPS participants and

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[4] 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); renewed October 1, 2009 (74 Fed. Reg. 51,279) (Oct. 6, 2009); renewed October 1, 2010 (75 Fed. Reg. 61,489) (Oct. 5, 2010).

[5] Authorization of Emergency Use of Oral Formulations of Doxycycline; Availability (76 Fed. Reg. 47,197) (Aug. 4, 2011).

[6] See footnote 1.

[7] In an effort to alleviate concerns for their households' safety and thus accelerate the quick preventive strike, pre-event provision of doxycycline to members of the USPS employees' households is a condition of participation specified by the unions that represent the USPS carriers (the National Association of Letter Carriers and the National Rural Letter Carriers Association) and endorsed by USPS management.

[8] Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack (75 Fed. Reg. 737) (Jan. 6, 2010).

their household members, i.e., anyone having permanent residence at the USPS participant's primary residential address.

The doxycycline hyclate tablet emergency kits for the NPM include both Household Antibiotic Kits (HAKs) and Individual Antibiotic Kits (IAKs).[9] Household Antibiotic Kits would be stored in eligible USPS participants' homes, contain unit-of-use bottles with a 10-day supply of doxycycline hyclate tablets for each eligible USPS participant and each eligible household member, and contain emergency use and home preparation instructions in a tamper-evident, transparent bag for secure storage. Each Individual Antibiotic Kit would be stored in a secure location under proper storage conditions at the eligible USPS participant's workplace in the event the USPS participant should need to deploy under the NPM immediately, contain one unit-of-use bottle with a 10-day supply of doxycycline hyclate tablets for the USPS participant, and contain 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. An EUA is needed to facilitate the NPM's pre-event planning and preparedness activities, which may include elements that would otherwise violate provisions of the FD&C Act under FDA's legal interpretations.[10]

Having consulted with the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), and having concluded that the criteria for issuance of this authorization under section 564(c) of the FD&C Act (21 U.S.C. § 360bbb-3(c)) are met, I authorized the emergency use of doxycycline hyclate tablet emergency kits, where not contraindicated, for the post-exposure prophylaxis[11] of inhalational anthrax for eligible USPS participants and their household members in the event of a public health emergency involving *B. anthracis*, subject to the terms of the authorization. By this letter, I am amending that authorization.[12] The amended EUA will apply in all circumstances in which a venue-specific Postal Plan under the NPM is in place.

The remainder of this letter is organized into five sections: (I) Criteria for Issuance of Authorization; (II) Scope of Authorization; (III) Current Good Manufacturing Practice (CGMP); (IV) Conditions of Authorization; and (V) Duration of Authorization.

I. Criteria for Issuance of Authorization

[9] Where referenced, "Individual Antibiotic Kit" (IAK) replaces "Individual Household Antibiotic Kit" (iHAK) included in the October 1, 2008, EUA, as amended.

[10] Such elements include, but are not limited to: distribution and use of emergency use information sheets, e.g., fact sheet for health care professionals, fact sheet for recipients, and fact sheet for recipients with home preparation instructions for recipients who cannot swallow pills; dispensing doxycycline without all of the required information on the prescription label per section 503(b)(2) (U.S.C. § 353(b)(2)); dispensing a partial supply of the full 60-day dosage regimen, i.e., initial start-up 10-day supply; and pre-event storage or distribution of doxycycline packaged or repackaged for emergency distribution.

[11] Prophylaxis is generally considered to apply in situations in which the person receiving the drug has not exhibited symptoms. Because, in many cases in which doxycycline may be used pursuant to this authorization, it will not be practical to distinguish between persons who have exhibited symptoms and those who have not, this authorization permits the administration of doxycycline to persons who may have been exposed to *B. anthracis* during a public health emergency whether or not they have begun to exhibit symptoms. We would expect that responsible authorities would direct any persons who have begun to exhibit symptoms to appropriate medical care as expeditiously as possible.

[12] FDA is authorizing the emergency use of FDA-approved formulations of doxycycline hyclate 100 mg oral tablets contained in doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax as described in the scope section of this letter (see Section II. Scope of Authorization).

I have concluded that the emergency use of doxycycline hyclate tablet emergency kits, where not contraindicated, for the post-exposure prophylaxis of inhalational anthrax for eligible USPS participants and their household members in the event of a public health emergency involving *B. anthracis* meets the criteria for issuance of an authorization under section 564(c) of the FD&C Act, because I have concluded that:

(1) *B. anthracis* can cause inhalational 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 the post-exposure prophylaxis of inhalational anthrax, 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 such products; and

(3) there is no adequate, approved, and available alternative to doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax.[13]

Therefore, 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 above statutory criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the FD&C Act, that the scope of this authorization is limited to the emergency use of doxycycline hyclate tablet emergency kits, where not contraindicated, by eligible USPS participants and their household members for purposes of pre-event planning and preparedness activities, and, in a post-event scenario, implementation of post-exposure prophylaxis for inhalational anthrax for eligible USPS participants and their household members who have been exposed, or who may have been exposed, to aerosolized *B. anthracis* spores. Eligible USPS participants include those employees who have agreed in writing to participate in the NPM, have been medically screened for contraindications based on completed USPS NPM Health Assessment Forms, have been given valid prescriptions, and have not otherwise been determined to be ineligible to receive doxycycline hyclate tablet emergency kits. Eligibility to receive doxycycline hyclate tablet emergency kits also must be determined for household members of eligible USPS participants. The emergency use of doxycycline hyclate tablet emergency kits under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below.

The authorized doxycycline hyclate tablets contained in the emergency kits include the following products:

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

FDA-approved formulations of doxycycline hyclate 100 mg oral tablets[14] that have been repackaged into unit-of-use bottles containing 20 oral tablets each, i.e., a 10-day supply, and relabeled[15] by HHS, and that have then been packaged into doxycycline hyclate tablet emergency kits by, or under the direction of, ASPR and, as appropriate, labeled with an expiration date based on the expiration date on the manufacturer's original container. The antibacterial drug dispensed to USPS participants will be refreshed no later than the expiration date of the repackaged product.

Doxycycline is a semisynthetic tetracycline antibacterial drug approved for prescription use by FDA for treatment and post-exposure prophylaxis of anthrax due to *B. anthracis*, including inhalational anthrax, to reduce the incidence or progression of disease following exposure to aerosolized *B. anthracis*.[16] The post-exposure prophylaxis indication generally means that drug administration is expected to start after a known or suspected exposure to aerosolized *B. 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 *B. anthracis* exposure via inhalation is expected and likely 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 document. Generally, once symptoms develop, the approved indication for "treatment" would apply. Although it is expected that NPM emergency use plans will, to the extent possible, direct symptomatic individuals to health care professionals for appropriate treatment, FDA recognizes that circumstances may necessitate the use of doxycycline hyclate tablet emergency kits by eligible individuals who may be symptomatic.

ASPR will determine whether to initiate distribution of doxycycline hyclate tablet emergency kits under this EUA to particular NPM locations based on pre-determined NPM program requirements.

1. The above doxycycline hyclate tablet emergency kits are authorized for pre-event storage and distribution, and for post-event storage, distribution, and use, when manufactured under CGMP requirements; when repackaged and relabeled under CGMP requirements (21 C.F.R. 211),[17] despite the fact that they may not contain all of the required information on the prescription label under section 503(b)(2) of the FD&C Act (21 U.S.C. § 353(b)(2)), e.g., name and address of dispenser, serial number, date of prescription or of its filling, name of prescriber, directions for use and cautionary statements, if contained in the prescription; and when then packaged into doxycycline hyclate tablet emergency kits by, or under the direction of, ASPR health care professionals.

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[14] FDA-approved drugs can be identified at the *Drugs at FDA* website at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.

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

[16] The full course of doxycycline tablets for adults for the post-exposure prophylaxis of inhalational anthrax is 100 mg twice daily for 60 days. Children weighing 40 kg or more (89 pounds or more) should receive the adult dose. Children weighing less than 40 kg should receive 2.2 mg/kg of body weight per dose, by mouth, twice daily (maximum 100 mg per dose).

[17] It is currently planned that such repackaging and relabeling will be handled by the HHS Supply Service Center at Perry Point, Maryland. This authorization would, however, permit such repackaging and relabeling at any other HHS-selected facility that meets CGMP requirements and the terms and conditions of this EUA.

2. The doxycycline hyclate tablet emergency kits previously referenced are authorized to be accompanied by authorized emergency use information, to be made available to health care professionals involved in the NPM and to eligible USPS participants and their household members, to facilitate understanding of anthrax disease and the risks and benefits of doxycycline therapy and to improve medication compliance. This information includes:

   - USPS NPM Doxycycline EUA Fact Sheet for Health Care Professionals
   - USPS NPM Doxycycline EUA Fact Sheet for Recipients
   - In an Emergency: How to Prepare Doxycycline for Children and Adults Who Cannot Swallow Pills[18]
   - USPS NPM Information Placard[19]
   - MedWatch Form 3500[20]

   Any revisions or additional written materials to be provided by ASPR, USPS, or the PPHA are subject to FDA's prior approval, except that ASPR may provide additional materials for recruitment and program management purposes, which may be updated to reflect programmatic changes, consistent with the following authorized attachments:

   - USPS NPM Health Assessment Form[21]
   - USPS NPM Health Care Professional Quality Checklist
   - USPS NPM Questions to Determine Status of the HAKs/IAKs
   - USPS NPM Exemption Form

3. The doxycycline hyclate tablet emergency kits previously referenced are authorized to be stored, distributed, and used as a partial supply,[22] i.e., 10-day supply, of a full 60-day dosage regimen, when stored, distributed, and used as part of the NPM.

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[18] *In an Emergency: How to Prepare Doxycycline for Children and Adults Who Cannot Swallow Pills* is available in a one-page or 2-page format (or as updated by FDA) at http://www.fda.gov/doxyprepare.

[19] ASPR may use the previously-authorized version of the Information Placard, so long as the revised version authorized by this EUA is used when supplies of the previously-authorized version are exhausted.

[20] The MedWatch Form 3500 is available at http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf and can be printed double sided to generate a form that can be folded so that a business reply address is displayed for mailing.

[21] ASPR may use the previously-authorized version of the Health Assessment Form, so long as the revised version authorized by this EUA is used when supplies of the previously-authorized version are exhausted.

[22] The required and FDA-approved duration of doxycycline therapy for post-exposure prophylaxis against inhalational anthrax is 60 days. An initial, partial supply of doxycycline may be utilized to facilitate rapid initiation of antimicrobial therapy. Thus, the partial dispensing of the required quantity of doxycycline to complete therapy duration will be allowed under this EUA. Once the antimicrobial susceptibility of the associated *B. anthracis* strain involved in the exposure has been determined per its minimum inhibitory concentration, and potential exposure to *B. anthracis* has been confirmed, an additional supply of doxycycline must be dispensed to individuals to allow the full 60-day antimicrobial post-exposure prophylaxis regimen. The individual will receive further instructions on whether

ASPR is also authorized to make available additional information relating to the emergency use of authorized doxycycline hyclate tablet emergency kits that is consistent with the terms of this letter of authorization. (See Section IV. Conditions of Authorization.)

I have concluded, pursuant to section 564(d)(2) of the FD&C Act, that it is reasonable to believe that the known and potential benefits of the authorized doxycycline hyclate tablet emergency kits, when used for the post-exposure prophylaxis of inhalational anthrax, outweigh the known and potential risks of such products for USPS participants and their household members.

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

Subject to the terms of this EUA and consistent with the Secretary of DHS's determination under section 564(b)(1)(A) of the FD&C Act and the Secretary of HHS's corresponding declaration under 564(b)(1) of the FD&C Act described above, the authorized doxycycline hyclate tablet emergency kits previously described are authorized for the post-exposure prophylaxis of inhalational anthrax for eligible USPS participants and their household members who have been exposed, or who may have been exposed, to aerosolized *B. anthracis* spores.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the FD&C Act or when the EUA is revoked under section 564(g) of the FD&C Act. When this EUA ceases to be effective, the doxycycline hyclate tablet emergency kits described herein will no longer be authorized for emergency use under this EUA.[23]

III. Current Good Manufacturing Practice

This authorization only covers doxycycline hyclate tablets contained in emergency kits that have been manufactured under CGMP requirements, and that have been repackaged and relabeled under CGMP requirements (21 C.F.R. 211) by, or under the direction of, HHS.[24] Doxycycline hyclate tablets, 100 mg, subject to the Department of Defense (DOD)-FDA Shelf Life Extension Program (SLEP), will not be used for repackaging.

The doxycycline hyclate tablet emergency kits should be stored by eligible USPS participants and their household members at or close to controlled room temperature 20°C to 25°C (68°F to

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the additional 50-day supply is necessary based on the results of the antimicrobial susceptibility and also instructions on where to obtain the 50-day supply of doxycycline.

[23] Pursuant to Section 564(f)(2) of the Act, 21 U.S.C. 360bbb-3(f)(2), continued use of a product authorized by this letter may continue after the expiration of this authorization to the extent found necessary by the patient's health care professional.

[24] See footnote 17.

77°F). All recipients will receive in writing, as part of the screening and dispensing procedures, specific recommendations about safe storage locations out of the reach of children and pets.

IV. Conditions of Authorization

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

ASPR

A. ASPR will provide the following written materials, as authorized under this EUA and as applicable, to health care professionals involved in the NPM, USPS participants and their eligible household members, USPS, and the principal public health authority (PPHA) for each participating municipality:

- USPS NPM Doxycycline EUA Fact Sheet for Health Care Professionals
- USPS NPM Doxycycline EUA Fact Sheet for Recipients
- In an Emergency: How to Prepare Doxycycline for Children and Adults Who Cannot Swallow Pills[25]
- USPS NPM Information Placard[26]
- USPS NPM Health Assessment Form[27]
- USPS NPM Health Care Professional Quality Checklist
- USPS NPM Questions to Determine Status of the HAKs/IAKs
- MedWatch Form 3500[28]
- USPS NPM Exemption Form

B. ASPR will be aware of and ensure that anyone storing and distributing doxycycline hyclate tablet emergency kits for preparedness and response purposes under this EUA is informed of and instructed on the actions necessary to enable them to comply with the terms and conditions of this EUA, such as data collection, recordkeeping, and records access. This includes making available to health care professionals the FDA-approved package insert[29] that covers the authorized doxycycline hyclate 100 mg oral tablets and informing its designees, USPS, and the PPHAs of their obligation to promptly report within 15 days, and to instruct recipients who have taken the medicine in their doxycycline hyclate tablet emergency kits to report, adverse events and medication errors

[25] See footnote 18.
[26] See footnote 19.
[27] See footnote 21.
[28] See footnote 20.
[29] FDA-approved package inserts for doxycycline hyclate tablets are available at www.dailymed.nlm.nih.gov.

to MedWatch directly through www.fda.gov/medwatch, by submitting the MedWatch Form 3500[30] included both inside and outside each doxycycline hyclate tablet emergency kit in hard copy, or by calling 1-800-FDA-1088. Any such report should identify the product as "doxycycline hyclate tablet emergency kit" and indicate that the product was used under the "USPS-NPM EUA" (United States Postal Service National Postal Model Emergency Use Authorization) by including a description of the event the abbreviations "USPS-NPM EUA" or "USPS-NPM Emergency Use Authorization." Recipients who have taken the medicine in their doxycycline hyclate tablet emergency kits should also be instructed to report any adverse event or medication error to their personal physician or emergency department and to the designated ASPR health care professional. ASPR will provide a supply of MedWatch Form 3500 to the PPHA for each participating municipality.

C. ASPR, with the assistance of USPS, will submit a report to FDA summarizing the information collected every 6 months for the USPS NPM Questions to Determine Status of the HAKs/IAKs items within 30 days of collecting such information.

D. ASPR will notify FDA of its decision to add a municipality or geographic area to the NPM and of its decision to initiate distribution of doxycycline hyclate tablet emergency kits under this EUA to particular locations.

E. ASPR will ensure that all NPM 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 FD&C Act and FDA regulations.

F. ASPR is also authorized to make available additional information, including additional recommendations and instructions, related to the emergency use of doxycycline hyclate tablet emergency kits as described in this letter of authorization, to the extent that additional recommendations and instructions are necessary to meet public health needs during a declared public health emergency involving *B. anthracis* and are reasonably consistent with, and do not exceed, the terms of this letter of authorization.

G. ASPR and its designated health care professionals will conduct medical screening of potential USPS participants and their immediate household members. ASPR, with assistance from USPS as necessary, will distribute USPS NPM Health Assessment Forms to identified USPS employee volunteers, which will include a section allowing for the volunteers to consent to direct shipment of their Individual Antibiotic Kits to USPS program staff for pre-positioning at their workplace. All household individuals must complete the screening form; caregivers will complete the form for children and other household members who are unable to complete the form. Designated ASPR health care professional(s) will review the medical history information with the USPS employee (either by telephone or in person, to establish a "therapeutic relationship"), provide two prescriptions for each employee, i.e., one for the employee's Household Antibiotic Kit and one for the employee's Individual Antibiotic Kit, and prescribe doxycycline for each member of the household for which the drug is appropriate or document that the USPS

[30] See footnote 20.

employee and/or the household member is not eligible for participation at this time, and transmit the prescription for each employee's Household Antibiotic Kit and Individual Antibiotic Kit to the designated pharmacy unit. ASPR will ensure that a designated pharmacist or other qualified person is also available to answer any questions the USPS employee may have regarding the prescription or its use.

USPS employees for whom doxycycline is contraindicated will be considered disqualified. However, if the contraindication applies only to one or more of the members of the USPS employee's household, then the USPS employee will be eligible to serve provided that he or she makes an informed choice. The employee will have the opportunity to inform ASPR in writing on the USPS NPM Exemption Form that he or she is prepared to accept an incomplete Household Antibiotic Kit and understands that, during a public health emergency involving exposure of his or her household to *B. anthracis*, the household member(s) not covered by the Household Antibiotic Kit will have the same dependency as does the rest of the community upon whatever emergency mass chemoprophylaxis the public health authority(ies) is able to provide. That is, the USPS employee will have the option to participate in the venue-specific Postal Plan and accept whatever degree of pre-event antimicrobial drug coverage is medically appropriate for the household, or decline to participate and accept for his or her entire household the same dependency upon the public health authority(ies) for emergency chemoprophylaxis as has the community, which will not have access to the Household Antibiotic Kits.

ASPR will ensure that USPS participants will be informed:

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

Supplying the information required to be provided with each doxycycline hyclate tablet emergency kit satisfies ASPR's obligation to inform USPS participants of this information.

H. ASPR will be responsible for procurement of doxycycline, for the receipt of prescriptions, for determining how many household members are eligible to receive doxycycline, and for the packaging of the doxycycline hyclate tablet emergency kits. The packaging for each kit requires two health care professionals who are qualified and licensed to dispense prescription products according to appropriate State pharmacy laws. ASPR will liaise directly with the designated health care professionals prescribing the kits. Packaging 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.

An ASPR health care professional will initially assemble the doxycycline hyclate tablet emergency kits as outlined in the USPS NPM Health Care Professional Quality Checklist, including by recording prescription information on the USPS NPM Health Assessment Form, by recording information about the bottles dispensed on a Drug Accountability/Inventory Record, by providing in and on the outside of each kit the applicable set of written information authorized by this EUA, and by labeling each unit-of-use bottle with the name of the eligible USPS participant or household member. Before dispensing, a different designated ASPR health care professional will, as outlined in the USPS NPM Health Care Professional Quality Checklist, check each doxycycline hyclate tablet emergency kit that has been assembled. The Household Antibiotic Kit for the USPS participant and his or her household will then be sent to the employee's home address using an accountable method of shipping, and, with the employee's consent, the Individual Antibiotic Kit for the USPS participant will be sent directly to USPS program staff.

I. ASPR must maintain a Drug Accountability/Inventory Record, including lot number, quantity, receiving site, and distribution date of the unit-of-use bottles of doxycycline shipped under this EUA for the recipients. ASPR will be responsible for recording names and contact information for each person to whom the doxycycline hyclate tablet emergency kits are dispensed. This requirement does not require record-keeping related to dispensing of doxycycline products to recipients during an emergency in those circumstances in which such record-keeping would not be consistent with an efficient program for the dispensing of the drug to recipients.[31] HHS will require the reporting of any adverse reactions to doxycycline. Likewise, HHS will provide FDA access to such records when requested.

J. ASPR, with assistance from the USPS as necessary, will, every 6 months dependent on the timing for refresh of the doxycycline hyclate tablet emergency kits, disseminate USPS NPM Questions to Determine Status of the HAKs/IAKs to the participating USPS employees for their written assurance that they have stored their kits as instructed, they are able to locate their kits readily, their kits are intact, if they or any of their household members have taken any of the medication in the kit (and, if so, whether they experienced any adverse events or medication errors), and the medication in their kits has not expired. ASPR will conduct an inquiry with USPS participants who report loss of a kit or use of doxycycline from the kit in the absence of instructions to do so to ascertain the circumstances of non-compliance. Depending on the findings, the USPS participant could be subject to disqualification from the further participation in the program.

For kits that will expire prior to the next 6-month data collection, a new doxycycline hyclate tablet emergency kit(s) will be dispensed to volunteers continuing on in the program using the original enrollment procedures, provided that the EUA is still in effect. In such cases, ASPR, assisted by USPS, will be responsible for ensuring that such kits are collected, accounted for, and disposed of, as instructed by ASPR. ASPR will maintain

[31] While such record-keeping is not a requirement of this EUA, it is expected that NPM participants will, to the extent possible, keep such records for purposes of their own follow-up of recipients, including for the purpose of assuring that any individual who has been provided less than a full course of doxycycline receives, if necessary, a full course.

drug accountability records. If the 6-month kit survey coincides with the timing of the refresh and the USPS participant returns the doxycycline hyclate tablet emergency kit(s) for refresh, a USPS NPM Questions to Determine Status of the HAKs/IAKs form will not need to be completed. ASPR will work with participants to make any necessary modifications to their respective kits based on their responses to the USPS NPM Questions to Determine Status of the HAKs/IAKs. ASPR will instruct USPS participants to return the kits, when they reach their date of expiry, using instructions in the USPS NPM Doxycycline EUA Fact Sheet for Recipients.

PPHA

K. The PPHA for each participating municipality may, in collaboration with ASPR, assist in coordinating NPM activities that occur within its jurisdiction, including by providing health care professionals and other personnel to assist ASPR health care professionals in screening, prescribing, and ensuring proper storage of doxycycline hyclate tablet emergency kits; by instructing participants to use the doxycycline hyclate tablet emergency kits during an actual emergency; by periodically verifying that the quantity of medication in storage corresponds with the Drug Accountability/Inventory Record (and reconciling any differences) and that all undistributed medication in the doxycycline hyclate tablet emergency kits is within its labeled expiration date; and by maintaining a supply of MedWatch Form 3500 for the purposes of reporting adverse events and medication errors.

USPS

L. USPS management and the unions representing mail carriers will solicit applicants jointly and will conduct the initial recruitment of USPS employee volunteers[32] by conducting oral briefings and providing written materials developed by or selected in consultation with ASPR. These materials include:

- the fact sheets and information associated with this EUA;
- an explanation of the NPM and its associated safety program, of which doxycycline hyclate emergency kits are a part;
- a form whereby the employees can indicate their decision to volunteer, to be collected by USPS officials, with possible assistance from local union leadership; and
- an example of a USPS NPM Health Assessment Form to help health care professionals identify possible contraindications for doxycycline.

USPS management and the unions representing mail carriers, in accord with the process for the initial recruitment, will invite new applicants, follow up appropriately with those who respond affirmatively, and confirm the status of those already enlisted in the program.

[32] Participation by USPS staff in a venue-specific Postal Plan is voluntary. No USPS staff will be required to accept either the risks of re-aerosolization during direct residential delivery of antimicrobial drugs in response to a wide-area anthrax emergency or the risks associated with possessing a pre-event kit of antimicrobial drugs for their household strictly for emergency use as directed.

M. USPS will not knowingly deploy carriers or supporting staff for emergency duty under a venue-specific Postal Plan without proper chemoprophylaxis. USPS will maintain Individual Antibiotic Kits for each eligible USPS participant in a secure cache in each Delivery Unit that is part of the venue-specific Postal Plan. USPS will allow access to Individual Antibiotic Kits only during a public health emergency for which they are appropriate and only as necessary to help ensure eligible USPS participants' safety.

N. USPS and its designees will be responsible for promptly reporting, within 15 days, any adverse event or medication error in recipients who have taken medication from their Household Antibiotic Kits or Individual Antibiotic Kits to MedWatch through www.fda.gov/medwatch, by submitting MedWatch Form 3500 in hard copy, or by calling 1-800-FDA-1088.

O. USPS will require that USPS participants who leave the employ of the USPS, e.g., through retirement or acceptance of other employment, or who no longer wish to volunteer for participation in their venue-specific Postal Plan, return their doxycycline hyclate tablet emergency kit(s) to ASPR.

P. USPS, upon termination of the declaration of emergency under section 564(b)(2) of the FD&C Act or upon revocation of this EUA under section 564(g) of the FD&C Act, will be responsible for collecting all doxycycline hyclate tablet emergency kits and turning them over to ASPR. ASPR will dispose of doxycycline hyclate emergency kits at that time. ASPR and the PPHA for each participating municipality will ensure that drug accountability records are maintained and reconciled. Such records will be made available to FDA for inspection when requested.

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.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Enclosures

cc: Robin Robinson, Ph.D., Director, BARDA

[FR Doc. 2011–30450 Filed 11–25–11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0488]

Determination That TAXOTERE (Docetaxel) Injection, 40 Milligrams/Milliliter Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that TAXOTERE (docetaxel) Injection, 40 milligrams/milliliter (mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for docetaxel injection, 40 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nam Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6320, Silver Spring, MD 20993–0002, (301) 796–3472.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

TAXOTERE (docetaxel) Injection, 40 mg/mL is the subject of NDA 20–449, held by Sanofi-aventis U.S., and initially approved on May 14, 1996. TAXOTERE is indicated for breast cancer, non-small cell lung cancer, hormone refractory prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck cancer as described in detail on the drug product's labeling.

TAXOTERE (docetaxel) Injection, 40 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Sandoz, Inc. (Sandoz), submitted a citizen petition dated June 21, 2011 (Docket No. FDA–2011–P–0488), under 21 CFR 10.30, requesting that the Agency determine whether TAXOTERE (docetaxel) Injection, 40 mg/mL, was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that TAXOTERE (docetaxel) Injection, 40 mg/mL was not withdrawn for reasons of safety or effectiveness. The petitioner Sandoz has identified no data or other information suggesting that TAXOTERE (docetaxel) Injection, 40 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TAXOTERE (docetaxel) Injection, 40 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TAXOTERE (docetaxel) Injection, 40 mg/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to TAXOTERE (docetaxel) Injection, 40 mg/mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0799]

Draft Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Use of Nucleic Acid Tests (NAT) on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Recovered Plasma, Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of Hepatitis B Virus (HBV), and Requalification of Donors Who Test HBV NAT Positive,'' dated November 2011. The draft guidance document provides recommendations on the use of FDA-licensed nucleic acid tests (NAT) to screen blood donors for hepatitis B virus (HBV) deoxyribonucleic acid (DNA) and recommendations for product testing and disposition, donor management, methods for donor requalification, and product labeling. In addition, the draft guidance provides notification that FDA considers the use of an FDA-licensed HBV NAT to be necessary to reduce adequately and appropriately the risk of transmission of HBV. The guidance is intended for blood establishments that