



## Memorandum

Date: August 22, 2018

To: Government Public Health and Emergency Response Stakeholders

From: RADM Denise Hinton, MS, BSN, Chief Scientist

Subject: Expiration Date Extensions of Certain Lots of Doxycycline Hyclate 100 mg Capsules Held in Strategic Stockpiles

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In April 2017, the U.S. Food and Drug Administration (FDA) issued draft guidance, *Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles: Draft Guidance for Government Public Health and Emergency Response Stakeholders* (“draft guidance”), to help enable government stakeholders to maintain strategic stockpiles of FDA-approved doxycycline tablets and capsules held for public health preparedness for an anthrax emergency response.<sup>1,2</sup> The draft guidance describes the doxycycline product that is eligible for expiry dating extensions and provides laboratory testing protocols, enabling government stakeholders to have specific lots of their stockpiled doxycycline tested to determine whether such product would be eligible for an expiration date extension of two (2) years.

Before an identified lot of doxycycline tested under the draft guidance may be used beyond its manufacturer labeled expiration date, FDA first must authorize the extension for that lot based on a review of a government stakeholder request that includes testing data.<sup>3,4</sup> If FDA authorizes

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<sup>1</sup> FDA. *Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles: Draft Guidance for Government Public Health and Emergency Response Stakeholders*. April 2017.

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM554506.pdf>.

<sup>2</sup> The draft guidance defines “government stakeholders” as the public health and/or emergency response agencies or their agents/delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundaries (e.g., city, county, tribal, territorial, State, or Federal), or functional range or sphere of authority (e.g., law enforcement, public health, military health) to prescribe, administer, deliver, distribute, hold, or dispense a medical product during an emergency situation.

<sup>3</sup> Section 564A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to extend the expiration dating of certain eligible stockpiled medical countermeasures (as defined in section 564A(a) of the FD&C Act) intended to support the nation’s ability to protect the public health or military preparedness and effectiveness. An expiration date extension must be supported by an appropriate scientific evaluation that is conducted or accepted by FDA. Under this authority, products with extended expiry dates will not be deemed unapproved, adulterated, or misbranded.

<sup>4</sup> Expiry dating extensions authorized under section 564A(b) of the FD&C Act are limited to the specific products/lots identified by FDA. For purposes of this memorandum, doxycycline is considered an eligible product under section 564A(a) of the FD&C Act because it is an FDA-approved drug, intended for use for anthrax post-exposure prophylaxis or treatment, and intended for use during the circumstances under which a determination of a significant potential for a domestic emergency involving a heightened risk of attack with *B. anthracis*, the biological agent that causes anthrax disease, was made in 2008 by the Secretary of Homeland Security under section 564(b)(1)(A) of the FD&C Act or under which a material threat determination for *B. anthracis* was made in 2004 by the Secretary of Homeland Security.

such a requested expiration dating extension, other government stakeholders holding the same lot(s) of the extended product identified by FDA may apply the same extension of shelf life to their own stockpiled lot(s) of doxycycline without testing such lot(s), so long as such stakeholders follow the applicable requirements and conditions described in Section III.E.4 of the draft guidance. Among these requirements is that all untested lots held by government stakeholders that apply an authorized extension to such lot(s) must have been stored according to the product's manufacturer labeled storage conditions for the entire time they were stockpiled; if not, the authorized extension will not apply to such untested lot(s).

On July 30, 2018, FDA received a request under the draft guidance to extend the manufacturer labeled expiration date of five (5) lots of doxycycline hyclate 100 mg capsules manufactured by West-Ward Pharmaceuticals (West-Ward) that have been stockpiled for anthrax preparedness under the manufacturer labeled storage conditions. The request stated that these lots were tested on June 28, 2018, in accordance with the Table 1 Testing Protocol described in Section of III.C.1 of the draft guidance.

Based on the data submitted to FDA in the July 30, 2018, request, FDA has concluded that, provided the products have been, and continue to be, properly stored according to the manufacturer's labeled storage conditions, it is scientifically supportable for the five (5) lots of doxycycline hyclate 100 mg capsules manufactured by West-Ward that are identified below in Table 1 to continue to be stockpiled and used by any government stakeholder through the new use dates listed in the table (i.e., 2 years from the date of testing) for anthrax emergency preparedness and response purposes. Any government stakeholder applying these extensions to their lots must follow all applicable requirements and conditions described in Section III.E.4 of the draft guidance.<sup>5</sup> For purposes of this expiry dating extension, the manufacturer's original labeling must state that the product was manufactured by West-Ward (e.g., "Manufactured by West-Ward Pharmaceutical Corp.").

FDA is not requiring or recommending that the doxycycline lots identified below in Table 1 be relabeled with their new use date or other information. However, if this product needs to be dispensed and used during an actual anthrax emergency response, it is expected that the appropriate government stakeholders will communicate to recipients of the doxycycline product identified in Table 1 that FDA has determined the product may be used beyond its manufacturer labeled expiration date through its new use date.<sup>6,7</sup> To help ensure patient safety if the identified

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<sup>5</sup> Under section 564A(b) of the FD&C Act, in addition to identifying each specific lot, batch, or other unit of the product for which extended expiration is authorized and the duration of the extension, FDA shall identify any other requirements or conditions it may deem appropriate for the protection of the public health (including related to product sampling, storage, packaging/repackaging, transport, labeling, notice to product recipients, recordkeeping, periodic testing/retesting, or product disposition). The draft guidance describes the requirements and conditions in detail.

<sup>6</sup> As described in the draft guidance, the recipient notice requirement may be met if applicable Centers for Disease Control and Prevention (CDC) Emergency Use Instructions (EUI) for doxycycline issued under section 564A(e) of the FD&C Act address the use of such product beyond its manufacturer labeled expiration date.

<https://www.cdc.gov anthrax/medical-care/emergency-use-doxycycline-ciprofloxacin.html>.

<sup>7</sup> Government stakeholders should also refer to FDA's April 2016 *Doxycycline Emergency Dispensing Order* for additional information about dispensing doxycycline tablets and capsules during an anthrax emergency. <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm495126.htm#doxy>.

lots of doxycycline need to be dispensed and used during a response, all lots of the product must have been—and must continue to be—properly stored according to the manufacturer’s labeled storage conditions.

**Table 1. West-Ward doxycycline hyclate 100 mg capsules eligible for use beyond the manufacturer’s labeled expiration date**

<b>Doxycycline Lot Number (West-Ward)</b>	<b>Manufacturer’s Original Labeled Expiry Date</b>	<b>New Use Date</b>
68788A	March 31, 2015	June 30, 2020
GS008914	March 31, 2018	June 30, 2020
GS008915	March 31, 2018	June 30, 2020
GS008916	April 30, 2018	June 30, 2020
GS008917	April 30, 2018	June 30, 2020

The extensions in this memorandum are limited to the five (5) lots listed above in Table 1. However, other medical countermeasures (MCMs) held in strategic stockpiles should continue to be properly stored and retained until further information is provided, and government stakeholders are encouraged to have their doxycycline product that is held beyond the manufacturer labeled expiration date tested under the draft guidance. Any future extensions under the draft guidance, if requested by a government stakeholder and authorized by FDA, will be posted on the FDA website.<sup>8</sup> If government stakeholders opt to discard their stockpiled MCMs that are being held beyond their labeled expiration dating, then such products should be properly disposed (e.g., to prevent possible misuse, antimicrobial resistance, etc.).

For questions related to this memorandum, please contact Brad Leissa at [brad.leissa@fda.hhs.gov](mailto:brad.leissa@fda.hhs.gov) or Brooke Courtney at [brooke.courtney@fda.hhs.gov](mailto:brooke.courtney@fda.hhs.gov).

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<sup>8</sup> [www.fda.gov](http://www.fda.gov) or <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm411446.htm>.