



Memorandum

Date: September 3, 2015

To: State and Local Public Health and First Responder Stakeholders

From: Luciana Borio, MD, Acting Chief Scientist

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

FDA is aware of expiry dating challenges faced by state and local public health and other response stakeholders¹ that strategically stockpile medical countermeasures (e.g., doxycycline, ciprofloxacin, oseltamivir) and remains committed to finding appropriate solutions to address such challenges. At this time, the federal Shelf-Life Extension Program (SLEP), which is managed by the U.S. Department of Defense, remains limited to federal stockpiles of drugs. To help inform the potential development of guidance to enable states to conduct their own third party stability testing of doxycycline stockpiled for public health preparedness and response purposes (i.e., similar to the 2004 FDA guidance for state and local governments on extending the shelf life of potassium iodide (KI) tablets),² as part of a limited pilot study FDA tested certain lots of doxycycline that are beyond their manufacturer labeled expiration date to assess testing methodologies and whether expiration dating extensions of the product might be feasible.

Based on its review of appropriate scientific data, 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 certain lots of doxycycline hyclate 100-mg capsules manufactured by West-Ward Pharmaceuticals (West-Ward) that are identified below in Table 1 to continue to be stockpiled and used by stakeholders through the new use dates listed in the table (i.e., 2 years from the date of testing or, for product that has not yet reached its manufacturer labeled expiry date, 2 years from the labeled expiry date) for public health emergency response purposes.³ For the purpose of expiry dating extensions, the manufacturer's

¹ For purposes of this memorandum, the term "stakeholders" refers to the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical boundaries (e.g., city, county, tribal, state, or federal), or functional range or sphere of authority (e.g., public health, law enforcement) to stockpile, prescribe, administer, deliver, distribute, or dispense an eligible product during an emergency situation.

² U.S. Food and Drug Administration. *Guidance for Federal Agencies and State and Local Governments: Potassium Iodide Tablets Shelf Life Extension*. March 2004.

<http://www.fda.gov/downloads/Drugs/.../Guidances/ucm080549.pdf>.

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

original labeling must state that the product was manufactured by West-Ward (e.g., “Mfd. by West-Ward Pharmaceutical Corp.”).

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

| Doxycycline Lot Number (West-Ward) | Manufacturer’s Original Labeled Expiry Date | New Use Date ⁴ |
|------------------------------------|---|---------------------------|
| 65503A | August 31, 2012 | October 31, 2016 |
| 66058A | December 31, 2012 | October 31, 2016 |
| 66639A | April 30, 2013 | October 31, 2016 |
| 66648A | April 30, 2013 | October 31, 2016 |
| 69833A | March 31, 2016 | March 31, 2018 |
| 69834A | April 30, 2016 | April 30, 2018 |

FDA requests that this memorandum be communicated by state public health agencies to their appropriate state and local medical countermeasure stakeholders. FDA is not requiring or recommending that the doxycycline lots identified 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 public health emergency response, it is expected that the appropriate state and local 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. To help ensure patient safety if the products are dispensed and used during a response, the identified products must have been—and must continue to be—properly stored according to the manufacturer’s labeled storage conditions.

At this time, FDA will not be testing any additional lots of doxycycline product outside of SLEP or accepting requests from states for testing their lots of stockpiled medical countermeasures, including doxycycline or other products. However, medical countermeasures in state strategic stockpiles should continue to be properly stored and retained until further information is provided. If states opt to discard of such product, then the product should be properly disposed of (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 or Brooke Courtney at brooke.courtney@fda.hhs.gov.

or condition involving a chemical, biological, radiological, or nuclear (CBRN) agent(s). 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). Expiry dating extensions issued 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.

⁴ The expiration dating extension for the 4 lots (i.e., 65503A, 66058A, 66639A, and 66648A) that are beyond their labeled expiry date as of the date of this memo is 2 years from the date of testing in October 2014. The expiration dating extension for the 2 lots (i.e., 69833A and 69834A) that are not yet beyond their labeled expiry date as of the date of this memo is 2 years from the labeled expiry date.