

Estimated Total Annual Burden Hours: 84 hours.

Additional Information: Copies of the proposed collection may be obtained by emailing OPREinfocollection@acf.hhs.gov. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

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, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-0762]

Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles; Guidance for Government Public Health and Emergency Response Stakeholders; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for government public health and emergency response stakeholders entitled “Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles.” This document provides guidance to government stakeholders on testing to extend the expiration date—under the Federal Food, Drug, and Cosmetic Act (FD&C Act)—of stockpiled doxycycline tablets and capsules for public health emergency preparedness and response

purposes for an anthrax emergency. This guidance has been prepared in response to requests from States asking FDA what would be necessary to provide confidence that stockpiled doxycycline tablets and capsules have retained their original quality beyond the manufacturer’s labeled expiration date so the replacement of stockpiled product could be deferred. This guidance and any resulting expiration date extensions authorized by FDA do not apply to doxycycline available commercially or otherwise held for any other nonemergency purpose. This guidance finalizes the draft guidance issued in April 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on April 25, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as

well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-D-0762 for “Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division

of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Frederick Ensor, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6652, Silver Spring, MD 20993-0002, 240-402-2733.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for government public health and emergency response stakeholders entitled “Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles.” A number of government public health and emergency response stakeholders maintain stockpiles of doxycycline tablets or capsules for post-exposure prophylaxis (PEP) or treatment of inhalational anthrax in the event of an anthrax emergency. States have asked FDA what would be necessary to provide confidence that stockpiled doxycycline tablets and capsules have retained their original quality (*i.e.*, purity and potency) beyond the manufacturer’s labeled expiration date so the replacement of stockpiled product could be deferred. This document provides guidance to government stakeholders on testing to extend the expiration date—under section 564A(b) of the FD&C Act (21 U.S.C. 360bbb-3a(b))—of stockpiled doxycycline tablets and capsules for public health emergency preparedness and response purposes for an anthrax emergency.

This guidance applies to both doxycycline monohydrate and doxycycline hyclate tablets and capsules equivalent to 50 milligrams (mg) and 100 mg of doxycycline that are indicated for PEP or treatment of inhalational anthrax. Where doxycycline is mentioned throughout this guidance, it is meant to include both the hyclate and monohydrate forms of the drug that are indicated for PEP or treatment of inhalational anthrax.

This guidance finalizes the draft guidance issued in April 2017. Those comments received on the draft guidance did not result in any policy changes but in some instances did result

in clarifying language in the final guidance document.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information has been approved under OMB control number 0910-0595.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: April 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-0934]

Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics With Continuous Outcomes; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics with Continuous Outcomes.” The draft guidance, when finalized, will represent the current thinking of FDA on adjusting for covariates in randomized clinical trials for drugs and biologics, focusing on

randomized clinical trials with continuous endpoints.

DATES: Submit either electronic or written comments on the draft guidance by June 24, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2019-D-0934 for “Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics with Continuous Outcomes.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov>