4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-0412]

Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax." The purpose of this draft guidance is to assist sponsors in the development of new drugs for the prophylaxis of inhalational anthrax. This draft guidance supersedes the draft guidance entitled "Inhalational Anthrax (Post-Exposure)--Developing Antimicrobial Drugs" issued in March 2002.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2016-D-0412 for "Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax; Draft Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this draft 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: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6244, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax." The purpose of this draft guidance is to assist sponsors in the development of new drugs to be administered to persons who have

inhaled Bacillus anthracis spores, but who have not yet manifested clinical evidence of disease, to prevent the development of inhalational anthrax disease. We refer to this indication as "prophylaxis of inhalational anthrax." This draft guidance describes approaches for the designs of the animal model efficacy studies and recognizes that drug development for the sole indication of prophylaxis of inhalational anthrax is possible.

This draft guidance supersedes the draft guidance for industry entitled "Inhalational Anthrax (Post-Exposure)--Developing Antimicrobial Drugs" published in March 2002 (2002 draft guidance). The 2002 draft guidance stated that drugs for the prophylaxis of inhalational anthrax would be approved under the accelerated approval regulations (21 CFR part 314, subpart H, for drugs and 21 CFR part 601, subpart E, for biological products), unless the drug already carried an anthrax indication. Shortly after the 2002 draft guidance issued, FDA amended its regulations to provide a regulatory mechanism to approve drugs and biological products when human efficacy studies are not ethical or feasible (part 314, subpart I, for drugs and part 601, subpart H, for biological products). These regulations are commonly referred to as the "animal rule."[1] This draft guidance states that drugs developed for prophylaxis of inhalational anthrax will be considered for approval under the animal rule regulations. Other changes from the 2002 draft guidance are incorporated into the appropriate sections of this guidance and are based on comments received to the docket for the 2002 draft guidance as well as recent developments in scientific information that pertain to drugs being developed for prophylaxis of inhalational anthrax.

[1] The animal rule regulations in this guidance specifically refer to part 314, subpart I, for drugs and part 601, subpart H, for biological products. In October 2015, FDA finalized the guidance for industry entitled "Product Development Under the Animal Rule" that contains general information and recommendations on the development and approval of products under the animal rule.

Issuance of this draft guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. 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.

II. The Paperwork Reduction Act of 1995

This draft 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 collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: February 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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