TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
203.11—Reimportation	1	1	1	0.5 (30 minutes)	1
203.30(a)(1) and (b)—Drug sample requests	61,961	12	743,532	0.06 (4 minutes)	44,612
203.30(a)(3), (a)(4), and (c)—Drug sample receipts	61,961	12	743,532	0.06 (4 minutes)	44,612
203.31(a)(1) and (b)—Drug sample requests	232,355	135	31,367,925	0.04 (2.5 minutes)	1,254,717
203.31(a)(3), (a)(4), and (c)—Drug sample receipts	232,355	135	31,367,925	0.03 (2 minutes)	941,038
203.37(a)—Falsification of records	50	4	200	0.25 (15 minutes)	50
203.37(b)—Loss or theft of samples	50	40	2,000	0.25 (15 minutes)	500
203.37(c)—Convictions	1	1	1	1	1
203.37(d)—Contact person	50	1	50	0.08 (5 minutes)	4
203.39(g)—Reconciliation report	1	1	1	1	1
Total					2,285,536

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section/Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
203.23(a) and (b)—Returned drugs	31,676	5	158,380	0.25 (15 minutes)	39,595
203.23(c)—Returned drugs documentation	31,676	5	158,380	0.08 (5 minutes)	12,670
203.30(a)(2) and 203.31(a)(2)—Practitioner verification	2,208	100	220,800	0.5 (30 minutes)	110,400
203.31(d)(1) and (2)—Inventory record and reconciliation report.	2,208	1	2,208	40	88,320
203.31(d)(4)—Investigation of discrepancies and losses	442	1	442	24	10,608
203.31(e)—Representatives lists	2,208	1	2,208	1	2,208
203.34—Administrative systems	90	1	90	40	3,600
203.37(a)—Falsification of drug sample records	50	4	200	6	1,200
203.37(b)—Loss or theft of drug samples	50	40	2,000	6	12,000
203.39(d)—Destroyed or returned drug samples	65	1	65	1	65
203.39(e)—Donated drug samples	3,221	1	3,221	0.5 (30 minutes)	1,611
203.39(f)—Distribution of donated drug samples	3,221	1	3,221	8	25,768
203.39(g)—Drug samples donated to charitable institutions.	3,221	1	3,221	8	25,768
203.50(a)—Drug origin statement	125	100	12,500	0.17 (10 minutes)	2,125
203.50(b)—Drug origin statement retention	125	100	12,500	0.5 (30 minutes)	6,250
203.50(d)—Authorized distributors of record	691	1	691	2	1,382
Total					343,570

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of Agency data, we retain the currently approved burden estimate for the information collection, as reflected in tables 1 and 2 above.

Dated: May 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–11113 Filed 5–23–18; 8:45 am]

BILLING CODE 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; 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 guidance for industry entitled ''Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax.'' The purpose of this guidance is to assist sponsors in the development of new drugs for the prophylaxis of inhalational anthrax. This guidance finalizes the draft guidance of the same name issued on February 16, 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on May 24, 2018.

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–2016–D–0412 for ''Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax.'' 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: 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, 301–796–1400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax.'' The purpose of this guidance is to assist sponsors in the development of new drugs to be administered to people who have or may have inhaled *Bacillus anthracis* spores, but who have not yet manifested clinical evidence of disease, to prevent the development of inhalational anthrax. This guidance clarifies that drugs for the prophylaxis of inhalational anthrax are to be considered for approval under the animal rule regulations because human efficacy trials are not ethical or feasible (21 CFR part 314, subpart I, for drugs, and 21 CFR part 601, subpart H, for biological products).

This guidance finalizes the draft guidance of the same name issued on February 16, 2016 (81 FR 7813). Changes made to the guidance took into consideration written and verbal comments received. In addition to changes primarily for clarification, the major changes are as follows: Clarity in defining specific populations that would receive a drug for prophylaxis of inhalational anthrax, for example, first responders who anticipate exposure to *Bacillus anthracis* spores and initiate drug therapy immediately before exposure. In addition, the guidance was updated to provide consistency with the guidance for industry entitled ''Product Development Under the Animal Rule'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm399217.pdf*).

Issuance of this 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 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 prophylaxis of inhalational anthrax. 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. The 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 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 guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: May 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–11117 Filed 5–23–18; 8:45 am]

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