product produced from living organisms. In cases of certain biological products (*e.g.,* Albumin, Plasma Protein Fraction, and therapeutic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for the protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of licensed biological products. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously in this document. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products including submissions for lot release, surveillance, licensing, or export. Based on information obtained from FDA's database system, approximately 79 manufacturers submitted samples and protocols in fiscal year (FY) 2017, under the regulations cited previously in this document. FDA estimates that approximately 75 manufacturers submitted protocols under § 610.2 and two manufacturers submitted protocols under the regulation (§ 660.6) for the other specific product. FDA received no submissions under §§ 660.36 or 660.46, however FDA is using the estimate of one protocol submission under each regulation in the event that protocols are submitted in the future.

The estimated total annual responses are based on FDA's final actions completed in FY 2017 for the various submission requirements of samples and protocols for the licensed biological products. The average burden per response is based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the average burden per response is based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the other protocols than under § 610.2. FDA estimates the burden of this information collection as follows:

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
610.2—Requests for Samples and Protocols; Official Release	75	86.267	6,470	3	19,410
660.6(b)—Protocols	2	3.5	7	5	35
660.36(a)(2) and (b)—Samples and Protocols	1	1	1	6	6
660.46(b)—Protocols	1	1	1	5	5
Total	79		6,479		19,456

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

Our estimated burden for the information collection reflects an overall increase of 764 hours and a corresponding increase of 262 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: May 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10052 Filed 5–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0238]

Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act; 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 final guidance for industry entitled ''Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Section 503B defines an outsourcing facility, in part, as ''a facility at one geographic location or address.'' FDA has received questions from outsourcing facilities and other stakeholders about the meaning of this term, such as whether multiple suites used for compounding human drugs at a single street address constitute one or multiple facilities, or whether a single location where human drugs are compounded can be subdivided into separate operations compounding under different standards. FDA is issuing this guidance to provide the Agency's current thinking on these questions and related issues regarding how to ensure that the compounding of drugs in an outsourcing facility occurs only in accordance with section 503B.

DATES: The announcement of the guidance is published in the **Federal Register** on May 11, 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–0238 for ''Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' 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: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Section 503B (21 U.S.C. 353b), added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Drug Quality and Security Act in 2013, created a new category of compounders called outsourcing facilities. Section 503B describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from three sections of the FD&C Act:

• Section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning labeling requirements);

• Section 505 (21 U.S.C. 355) (concerning drug approval requirements); and

• Section 582 (21 U.S.C. 360eee–1) (concerning Drug Supply Chain Security Act requirements).

Section 503B(d)(4) of the FD&C Act defines an outsourcing facility as a facility at one geographic location or address that: (1) Is engaged in the compounding of sterile drugs; (2) has elected to register as an outsourcing facility; and (3) complies with all of the requirements of this section. In addition, an outsourcing facility is not required to be a licensed pharmacy, and it may or may not obtain prescriptions for identified individual patients. Because drugs compounded by outsourcing facilities are not exempt from section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), outsourcing facilities are subject to current good manufacturing practice requirements.

FDA has received questions from outsourcing facilities and other stakeholders about the meaning of the term ''facility at one geographic location or address,'' such as whether multiple suites used for compounding human drugs at a single street address constitute one or multiple facilities, or whether a single location where human drugs are compounded can be subdivided into separate operations compounding under different standards. FDA is issuing this guidance to provide its current thinking on these questions and related issues regarding how to ensure that the compounding of drugs in an outsourcing facility occurs only in accordance with section 503B.

In the **Federal Register** of April 18, 2016 (81 FR 22611), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on July 18, 2016. FDA received 19 comments on the draft guidance. In response to received comments, FDA made certain changes. In particular, FDA revised the guidance to provide for a compounder seeking to operate under section 503A of the FD&C Act (21 U.S.C. 353a) to be located next to an outsourcing facility provided that there is complete segregation between the outsourcing facility and the 503A compounder.

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 ''Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' 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. 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 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10046 Filed 5–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0407]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pilot Project Program Under the Drug Supply Chain Security Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by June 11, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Pilot Project Program Under the Drug Supply Chain Security Act.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

The DSCSA Pilot Project Program

OMB Control Number 0910—NEW

FDA will be establishing the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) Pilot Project Program to implement section 582(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee–1). This program will assist FDA in developing an interoperable, electronic system to identify and trace certain prescription drugs as the drugs are distributed in the United States by the year 2023. The Pilot Project Program goals include assessing the ability of supply chain members to: (1) Satisfy the requirements of section 582 of the FD&C Act; (2) identify, manage, and prevent the distribution of suspect and illegitimate products as defined in section 581(21) and (8) of the FD&C Act (21 U.S.C. 360eee(21) and (8)), respectively; and (3) demonstrate the electronic, interoperable exchange of product tracing information across the pharmaceutical distribution supply chain, in addition to identifying the system attributes needed to implement the requirements of section 582 of the FD&C Act, particularly the requirement to utilize a product identifier for product tracing purposes. FDA plans to coordinate with stakeholders that reflect the diversity of the pharmaceutical distribution supply chain, including large and small entities from all industry sectors.

Title: The DSCSA Pilot Project Program.

Description of Respondents: Respondents of this collection of information are participants from the pharmaceutical distribution supply chain (authorized manufacturers, repackagers, wholesale distributors, and dispensers) and other stakeholders.

Background Information: FDA will be seeking pilot project participants from the pharmaceutical distribution supply chain (authorized manufacturers, repackagers, wholesale distributors, and dispensers) and other stakeholders. FDA expects that participants will propose the design and execution of their pilot project in their submission to FDA; however, FDA also intends to meet with all pilot project participants to ensure that lessons learned from the pilot project(s) will inform FDA's development of the electronic, interoperable system that will take effect in 2023. FDA encourages supply chain members to focus their proposed pilot project(s) on the DSCSA requirements related to the interoperable, electronic tracing of products at the *package level.* Specifically, the pilot project(s) should focus on the requirements for package-level tracing and verification that take effect in 2023. Such pilot projects will be more useful than pilot projects dedicated to lot-level tracing. If there are adequate pilot project submissions, FDA may establish more than one pilot project to accomplish the goals of the DSCSA Pilot Project Program.

Because there is an information collection under the PRA associated with the DSCSA Pilot Project Program, this **Federal Register** notice is being issued as part of the process for OMB approval to collect this information. After OMB approval of this information collection, FDA will accept applications to participate in the program and will select qualified applications. FDA will announce OMB's approval in the **Federal Register**, the date that applications may be submitted, and application submission procedures.

In the **Federal Register** of July 20, 2017 (82 FR 33497), FDA published a 60-day notice requesting public comment on the proposed collection of information. A summary of the comments and FDA's responses are as follows.

(Comment 1) Several comments raised concerns with the proposed timelines related to initiation of pilot projects, duration of pilot projects, and final reports. One comment expressed concern that 4 months (after receiving a letter of acceptance from FDA) may not be enough time for a potential participant to be ready to initiate their pilot project. Another comment suggested that the proposed duration of pilot projects (no more than 6 months) should be longer and FDA should give the participant(s) more flexibility to conduct the pilot project. In addition, another comment expressed concern with the proposed requirement that final reports be completed within 30 days, because that may not be enough time to complete a final report.

(Response 1) The proposed timelines were intended to enable completion of FDA's Pilot Project Program within 1 year of the start date. FDA would like to complete the program in a timely manner so that the information learned can be shared and utilized by supply chain participants as they prepare and implement remaining DSCSA requirements that take effect between 2018 and 2023. To optimize the program, FDA expects pilot project participants to be ready to initiate their pilot project within 4 months after receiving a letter of acceptance from FDA. This will help ensure that participants have worked out funding, resources, planning, and other issues in advance of initiation of the pilot project. FDA provided flexibility in the program