requested, as set forth in Sec. 806 [42 U.S.C. 2991d–1](a)(1).

Respondents: Federally and state-recognized tribes, Native Pacific Islanders, Tribal Colleges and Universities, native non-profits, and consortia.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Objective Work Plan	300	1	3	900	300
Ongoing Progress Report FY 2020	200	2	1	400	133
Ongoing Progress Report FY 2021—Exp. Date	200	4	2	1600	533

* Burden is annualized over the three year approval period.

Estimated Total Annual Burden Hours: 966.

Authority: Sec. 806 [42 U.S.C. 2991d–1](a)(1) and Sec. 811 [42 U.S.C. 2992].

John M. Sweet Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–18219 Filed 8–19–20; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1429]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Human Drug Compounding Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act and Associated Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection pertaining to the registration of human drug compounding outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and associated fees.

DATES: Submit either electronic or written comments on the collection of information by October 19, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 19, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 19, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2013–N–1429 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act and Associated Fees.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Registration of Human Drug Compounding Outsourcing Facilities and Associated Fees Under Section 503B of the FD&C Act

OMB Control Number 0910–0776—Revision

This information collection helps to support implementation of section 503B of the FD&C Act and the Drug Quality and Security Act (DQSA).

A. Registration

Under section 503B of the FD&C Act (21 U.S.C. 353b), added by DQSA, a facility that compounds drugs may elect to register with FDA as an outsourcing facility. Drug products compounded in a registered outsourcing facility can qualify for exemptions from the FDA-approval requirements in section 505 of the FD&C Act (21 U.S.C. 355), the requirement to label products with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and the requirements for drug supply chain security in section 582 of the FD&C Act (21 U.S.C. 360eee–1) if the requirements in section 503B of the FD&C Act have been met.

After the initial registration, under section 503B(b) of the FD&C Act, a facility that elects to register with FDA as an outsourcing facility must also do so annually between October 1 and December 31. Upon registration, the outsourcing facility must provide specific information including its name, place of business, a unique facility identifier, and a point of contact's email address and phone number. The outsourcing facility must also indicate: (1) Whether it intends to compound, within the next calendar year, a drug that appears on our drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e); and (2) whether it compounds from bulk drug substances and, if so, whether it compounds sterile or non-sterile drugs from bulk drug substances.

Outsourcing facilities that elect to register submit registration information for each facility electronically using a Structured Product Labeling (SPL) format in accordance with the FDA guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing (May 2009).'' The guidance is available from our website at: *https://www.fda.gov/media/71146/download.* Respondents unable to use electronic means to register may submit a written request for a waiver from the requirement.

B. Registration Fees

Upon registration, and in accordance with section 503B and 744K of the FD&C Act, facilities are assessed an establishment fee and receive an annual invoice from FDA with instructions for remitting payment. Until payment is made for each given fiscal year (FY), an establishment is not considered to be registered as an outsourcing facility.

In accordance with section 744K of the FD&C Act (21 U.S.C. 379j–62), certain outsourcing facilities may qualify for a small business reduction in the amount of the annual establishment fee. To qualify for this reduction, an outsourcing facility must submit a written request to FDA certifying that the entity meets the requirements for the reduction. For each FY a firm seeks to qualify as a small business and receive the fee reduction, it must submit to FDA a written request by April 30 of the preceding FY. For example, an outsourcing facility must have submitted a written request for the small business reduction by April 30, 2020, to qualify for a reduction in the fiscal year 2021 annual establishment fee.

Section 744K also requires an outsourcing facility to submit written requests for a small business reduction in a specified format: Form FDA 3908 entitled ''Outsourcing Facilities for Human Drug Compounding: Small Business Establishment Fee Reduction Request.'' Form FDA 3908 is available from our website at: *https://www.fda.gov/media/90740/download.* In response to the submission of a small business reduction request, FDA will send a notification letter of its decision and recommends that applicants retain the notification.

C. Reinspection Fees

In accordance with section 503B, outsourcing facilities are subject to inspection and, in accordance with section 744K, subject to reinspection fees. A reinspection fee will be incurred for each reinspection and is intended to reimburse FDA when a particular outsourcing facility requires reinspection because of noncompliance identified during a previous inspection. After a reinspection is conducted, FDA will send an invoice to the email address indicated in the facility's registration file. The invoice contains instructions for remitting the reinspection fee.

D. Dispute Resolution

Agency regulations under § 10.75 (21 CFR 10.75) provide for internal Agency review of decisions. Accordingly, an outsourcing facility may request reconsideration of an FDA decision related to the fee provisions of section 744K of the FD&C Act. Requests for reconsideration should include the facility's rationale for its position that FDA's decision was in error and include any additional information that is relevant to the outsourcing facility's assertion. The denial of a request for reconsideration may be appealed by submitting a written request to FDA, consistent with § 10.75.

To assist respondents with the information collection provisions, we have developed Agency guidance. The guidance document, entitled ''Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act (November 2014),'' describes the process for electronic submission of establishment registration information for outsourcing facilities and provides information on how to obtain a waiver from submitting registration information electronically. The guidance document, entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act (November 2014),'' describes the types and amounts of fees that outsourcing facilities must pay, the adjustments to fees required by law, how outsourcing facilities can submit payment to FDA, the consequences of outsourcing facilities' failure to pay fees, and how an outsourcing facility can qualify as a small business to obtain a reduction in fees. The guidance documents were issued consistent with our good guidance practice regulations (21 CFR 10.115), which provide for public comment at any time, and are available on our website at *https://www.fda.gov/media/87570/download* and *https://www.fda.gov/media/136683/download,* respectively.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic Submission of Registration Information Using the SPL Format.	70	1	70	4.5	315
Waiver Request From Electronic Submission of Registration Information.	1	1	1	1	1
Subtotal					
Remission of Annual Establishment Fee From FDA Invoice.	70	1	70	0.5 (30 minutes)	35
Request for Small Business Reduction (Form FDA 3908).	15	1	15	25	375
Reinspection Fees	14	1	14	0.5 (30 minutes)	7
Reconsideration Requests	1	1	1	1	1
Appeal of Reconsideration Denials	1	1	1	1	1
Total			101		419

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

We estimate 70 respondents annually will submit outsourcing facility registrations using the SPL format as specified in Agency guidance and assume each registration will require 4.5 hours to prepare and complete. We expect no more than one waiver request from the electronic submission requirement annually and assume each waiver request will require 1 hour to prepare and submit. We estimate each of the 70 registrants will remit annual establishment fees and assume this task requires 30 minutes per respondent. We estimate that 15 of those respondents will request a small business reduction in the amount of the annual establishment fee using Form FDA 3908.

We estimate 14 outsourcing facilities annually will remit reinspection fees and assume this will require 30 minutes. We also estimate that we will receive three requests for reconsideration and one appeal of a denial of a request for reconsideration and assume 1 hour per respondent for this activity.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Retention of small business designation notification letter.	15	1	15	0.5 (30 minutes)	7.5

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

We estimate that annually 15 outsourcing facilities will maintain a copy of their small business designation letter and that maintaining each record will require 0.5 hour (30 minutes).

These estimates reflect a slight increase in the number of annual registrations, but a decrease in reinspection fee submissions.

Dated: August 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–18254 Filed 8–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1727]

Public Meeting on the Center for Drug Evaluation and Research Standard Core Sets: Clinical Outcome Assessments and Endpoints Grant Program—Summer 2020; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public meeting entitled ''Public Meeting on CDER Standard Core Sets: Clinical Outcome Assessments and Endpoints Grant Program—Summer 2020.'' The purpose of the public meeting is to ensure that as standard core sets of clinical outcome assessments (COAs) are developed as part of the FDA pilot grant program, the identified concepts, COAs, and endpoints reflect what is most important to patients and relevant to regulatory and potentially other stakeholder decision making. To facilitate this, stakeholders including patients, care partners, FDA reviewers, drug developers, as well as other government and academic researchers, health care providers, health technology assessors and health payers are encouraged to attend the meeting.

DATES: The public meeting will be held on Friday, August 28, 2020, from 8:30 a.m. to 12:30 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by Wednesday, October 28, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this public meeting via an online teleconferencing platform.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1727. The docket will close on October 28, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before Wednesday, October 28, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of Wednesday, October 28, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2020–N–1727 for ''Public Meeting on CDER Standard Core Sets Clinical Outcome Assessments and Endpoints Grant Program—Summer 2020.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Lyna Merzoug, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6308, Silver Spring, MD 20993–0002, 301–796–6001, *CDER_StandardCoreCOAs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

As part of our Patient Focused Drug Development (PFDD) efforts, FDA developed a pilot grant program to support the development of publicly available standard core set(s) of COAs