ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application	52	1	40	2,080
Annual Report	52	1	24	1,248

Estimated Total Annual Burden Hours: 3,328.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary Jones,

ACF/OPRE Reports Clearance Officer.

[FR Doc. 2017–22294 Filed 10–13–17; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0329]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Fees for Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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.

DATES: Fax written comments on the collection of information by November 15, 2017.

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 0910–0776. 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, 10A63, 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.

Guidance for Industry on Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act OMB Control Number 0910–0776—Extension

This information collection supports the Agency's guidance on fees for human drug compounding outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). On November 27, 2013, the President signed the Drug Quality and Security Act (DQSA) (Pub. L. 113–54) into law. The DQSA added a new section, 503B (21 U.S.C. 353B), to the FD&C Act, creating a category of entities called ''outsourcing facilities.'' Outsourcing facilities, as defined in section 503B(d)(4) of the FD&C Act, are facilities that meet certain requirements described in section 503B, including registering with FDA as an outsourcing facility and paying associated fees. Drug products compounded in an outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act (21 U.S.C. 355), and 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)), if the requirements in section 503B of the FD&C Act are met.

The guidance is intended for entities that compound human drugs and elect to register as outsourcing facilities under section 503B of the FD&C Act. Once an entity has elected to register as an outsourcing facility, it must pay certain fees to be registered as an outsourcing facility. The guidance describes the types and amounts of fees that outsourcing facilities must pay, the adjustments to fees required by law, the way in which outsourcing facilities may submit payment to FDA, the consequences of outsourcing facilities' failure to pay fees, and the way an outsourcing facility may qualify as a small business to obtain a reduction in fees.

In the **Federal Register** of June 15, 2017 (82 FR 27493), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received. We therefore estimate the burden associated with the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—ESTABLISHMENT FEE [1]

Type of reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Payment of annual establishment fee	60	1	60	.5 (30 minutes)	30
Request for Small Business Establishment Fee Reduction (Form FDA 3908)	15	1	15	25	375
Total					405

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN—RE-INSPECTION FEE AND DISPUTE RESOLUTION REQUESTS [1]

Type of reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Payment of re-inspection fee	15	1	15	.5 (30 minutes)	7.50
Reconsideration request	3	1	3	1	3
Appeal request	1	1	1	1	1
Total					11.50

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

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of recordkeeping	Number of recordkeepers	Number of record per recordkeeper	Total annual records	Average burden per record	Total hours
Copy of small business designation letter	15	1	15	.5 (30 minutes)	7.50

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

As described in section III.A of the guidance, upon receiving registration information from a facility seeking to register as an outsourcing facility, FDA will send an invoice for an establishment fee to the outsourcing facility. The invoice contains instructions for paying the establishment fee, as discussed in section III.E of the guidance. This process would be repeated annually under the timeframes described in the guidance. An outsourcing facility is not considered registered until the required establishment fee is paid for that fiscal year.

We estimate that annually a total of 60 outsourcing facilities (''no. of respondents'' in table 1, row 1) will pay to FDA 60 establishment fees (''total annual responses'' in table 1, row 1) as described in the guidance. We also estimate that it will take an outsourcing facility 0.5 hour to prepare and submit to FDA each establishment fee (''average burden per response'' in table 1, row 1).

As described in section III.C of the guidance, outsourcing facilities that are re-inspected will be assessed a re-inspection fee for each re-inspection. The re-inspection fee is designed to reimburse FDA when it must visit a particular outsourcing facility more than once because of noncompliance identified during a previous inspection. A re-inspection fee will be incurred for each re-inspection that occurs. After FDA conducts a re-inspection, we will send an invoice to the email address indicated in the facility's registration file. The invoice contains instructions for paying the re-inspection fee, as discussed in section III.E of the guidance.

We estimate that annually a total of 15 outsourcing facilities (''no. of respondents'' in table 2, row 1) will pay to FDA 15 re-inspection fees (''total annual responses'' in table 2, row 1) as described in the guidance. We also estimate that it will take an outsourcing facility 0.5 hour to prepare and submit to FDA each re-inspection fee (''average burden per response'' in table 2, row 1).

As described in section III.D of the guidance, 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 to FDA a written request certifying that the entity meets the requirements for the reduction. For every fiscal year that the firm seeks to qualify as a small business and receive the fee reduction, the written request must be submitted to FDA by April 30 of the preceding fiscal year. For example, an outsourcing facility must submit a written request for the small business reduction by April 30, 2015, to qualify for a reduction in the fiscal year 2016 annual establishment fee. As described in the guidance, section 744K of the FD&C Act (21 U.S.C. 379j–62) also requires an outsourcing facility to submit its written request for a small business reduction in a format specified by FDA in the guidance. The guidance specifies that Form FDA 3908 is the format for submitting requests for a small business fee reduction.

We estimate that annually a total of 15 outsourcing facilities (''no. of respondents'' in table 1, row 2) will submit to FDA a request for a small business reduction in the amount of the annual establishment fee. We estimate that 15 outsourcing facilities will submit Form FDA 3908 (''total annual responses'' in table 1, row 2) to FDA annually, as described in the guidance, and that it will take an outsourcing facility 25 hours to prepare and submit to FDA each Form FDA 3908 (''average burden per response'' in table 1, row 2).

As described in section III.D of the guidance, those outsourcing facilities that request a small business reduction in the amount of the annual establishment fee will receive a small business designation letter notifying the facility of FDA's decision. Outsourcing facilities eligible to pay a reduced fee should maintain a copy of the small business designation letter applicable to that fiscal year for their records.

We estimate that annually a total of 15 outsourcing facilities (''no. of recordkeepers'' in table 3) will keep a copy of their small business designation letter (''total annual records'' in table 3), and that maintaining each record will take 0.5 hour (''average burden per recordkeeping'' in table 3).

As described in section V.B of the guidance, an outsourcing facility may request reconsideration under 21 CFR 10.75 of an FDA decision related to the fee provisions of section 744K of the FD&C Act. As explained in the guidance, the request should state the facility's rationale for its position that the decision was in error and include any additional information that is relevant to the outsourcing facility's argument.

We estimate that a total of three outsourcing facilities (''no. of respondents'' in table 2, row 2) annually will submit to FDA a request for reconsideration as described in the guidance. We estimate that it will take an outsourcing facility approximately 1 hour to prepare and submit to FDA each request for reconsideration (''average burden per response'' in table 2, row 2).

As described in section V.B of the guidance, an outsourcing facility may appeal, as set forth in § 10.75, an FDA denial of a request for reconsideration of an FDA decision related to the fee provisions of section 744K of the FD&C Act.

We estimate that a total of one outsourcing facility (''no. of respondents'' in table 2, row 3) annually will submit an appeal of an FDA denial of a request for reconsideration. We estimate that it will take an outsourcing facility 1 hour to prepare and submit each appeal under § 10.75 (''average burden per response'' in table 2, row 3).

Dated: October 10, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–22283 Filed 10–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1429]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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.

DATES: Fax written comments on the collection of information by November 15, 2017.

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 0910–0777. 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.

Guidance for Industry on Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act OMB Control Number 0910–0777—Extension

This information collection supports the above captioned Agency guidance. A facility that compounds drugs may elect to register with FDA as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353b), as added by the Drug Quality and Security Act (DQSA). 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 drug supply chain security requirements in section 582 of the FD&C Act (21 U.S.C. 360eee) if the requirements in section 503B of the FD&C Act are 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 its name, place of business, a unique facility identifier, and a point of contact email address and phone number. The outsourcing facility must also indicate whether it intends to compound, within the next calendar year, a drug that appears on FDA's drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e), and 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 should submit the following registration information to FDA for each facility:

- Name of the facility;
- Place of business;
- Unique facility identifier;
- Point of contact email address and phone number;
- Whether the facility intends to compound drugs that appear on FDA's drug shortage list in effect under section 506E of the FD&C Act; and
- An indication of whether the facility compounds from bulk drug substances, and if so, whether it compounds sterile or nonsterile drugs from bulk drug substances.

Registration information should be submitted to FDA electronically using the Structured Product Labeling (SPL) format and in accordance with section IV of the FDA guidance entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.'' Under the final guidance, outsourcing facilities may request a waiver from the SPL electronic submission process by submitting a written request to FDA explaining why the use of electronic means is not reasonable.

In the **Federal Register** of June 20, 2017 (82 FR 28076), FDA published a 60-day notice requesting public