4164-01-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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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	No. of Respondents	No. 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	No. of Respondents	No. 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	No. of Recordkeepers	No. of Records 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.

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