



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0329]

Agency Information Collection Activities; Proposed Collection; 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 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 the information collection in the guidance on Fees for Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

REGISTER]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2014-D-0329 for "Guidance for Industry on Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the Federal Food, Drug, and Cosmetic Act." 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 Division of Dockets Management 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 Division of

Dockets Management. 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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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: Under the PRA (44 U.S.C. 3501-3520), 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.

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

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.

The guidance contains the following collections 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).

The estimated reporting and recordkeeping burdens for this collection of information are as follows:

Table 1.--Estimated Annual Reporting Burden--Establishment Fee¹

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 (FDA Form 3908)	15	1	15	25	375
Total					405

¹There 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 Requests¹

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

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

Table 3.--Estimated Annual Recordkeeping Burden¹

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

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

Dated: June 9, 2017.

Anna K. Abram,

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

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