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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–07237 Filed 3–31–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0329]

Guidance for Industry on Fees for Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' The guidance is intended for entities that compound human drugs and elect to register as outsourcing facilities (outsourcing facility) under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Drug Quality and Security Act (DQSA). Entities that elect to register as outsourcing facilities must pay certain fees to be considered outsourcing facilities. This guidance describes the annual establishment fee, the reinspection fee, annual adjustments to fees required by law, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee.

DATES: Submit either electronic or written comments on FDA guidances at any time. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by June 2, 2014.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of User Fee Management and Budget Formulation, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Rm. 2163, Silver Spring, MD 20903. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: M. Jonathan Gil, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20903, 301–796–7900.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' On November 27, 2013, President Obama signed the DQSA (Pub. L. 113–54) into law. The DQSA added a new section 503B to the FD&C Act that created 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 conditions described in section 503B(a), including, registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from two sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (2) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

This guidance describes in detail the fee types and amounts an entity must pay to satisfy the fee requirements of sections 503B(a)(9) and 744K of the FD&C Act to be deemed an outsourcing facility and maintain its status as an outsourcing facility, the adjustments to the fees required by law, how to qualify as a small business to obtain a reduction of the annual establishment fee, how and when to submit payment to FDA, the effect of failure to pay fees, and fee-related dispute resolution.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection are given under this section with an estimate of the reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We invite 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.

Title: Guidance for Industry on Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act; Availability.

Description: The draft guidance pertains to entities that compound human drugs and elect to register as outsourcing facilities. These outsourcing facilities must pay certain fees to FDA. The draft guidance describes the fee

types and amounts, the adjustments to fees required by law, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee. The draft guidance contains the following collections of information:

1. As described in section III.A of the draft 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 draft guidance. This process would be repeated annually under the timeframes described in the draft 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 approximately 20 outsourcing facilities (''no. of respondents'' in table 1, row 1) will pay to FDA approximately 20 establishment fees (''total annual responses'' in table 1, row 1) as described in the draft guidance. We also estimate that it will take an outsourcing facility approximately 0.5 hours to prepare and submit to FDA each establishment fee (''average burden per response'' in table 1, row 1).

2. As described in section III.C of the draft guidance, outsourcing facilities that are reinspected will be assessed a reinspection fee for each reinspection. The reinspection 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 reinspection fee will be incurred for each reinspection that occurs. After FDA conducts a reinspection, we will send an invoice to the email address indicated in the facility's registration file. The invoice contains instructions for paying the reinspection fee, as discussed in section III.E of the draft guidance.

We estimate that annually a total of approximately 5 outsourcing facilities (''no. of respondents'' in table 2, row 1) will pay to FDA approximately 5 reinspection fees (''total annual responses'' in table 2, row 1) as described in the draft guidance. We also estimate that it will take an outsourcing facility approximately 0.5 hours to prepare and submit to FDA each reinspection fee (''average burden per response'' in table 2, row 1).

3. As described in section III.D of the draft 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 and a certification 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 the fiscal year. For example, an outsourcing facility must submit a written request for the small business reduction by April 30, 2014, to qualify for a reduction in the fiscal year 2015 annual establishment fee. As described in the guidance, section 744K of the FD&C Act 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 draft guidance specifies that Form FDA 3908 is the format for submitting requests for a small business fee reduction; Form FDA 3908 is attached as Appendix 1.

We estimate that annually a total of approximately 10 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 approximately 10 Form FDA 3908 (''total annual responses'' in table 1, row 2) will be submitted to FDA annually, as described in the draft guidance, and that it will take an outsourcing facility approximately 25 hours to prepare and submit to FDA each Form FDA 3908 (''average burden per response'' in table 1, row 2).

4. As described in section III.D of the draft 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 approximately 10 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 approximately 0.5 hours (''average burden per recordkeeping'' in table 3).

5. As described in section V.B of the draft guidance, an outsourcing facility may request a 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 draft 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 approximately 2 outsourcing facilities (''no. of respondents'' in table 2, row 2) will submit to FDA a request for reconsideration as described in the draft guidance. We estimate that approximately 1 request for reconsideration (''total annual responses'' in table 2, row 2) will be submitted to FDA by each facility, and 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).

6. As described in section V.B of the draft guidance, an outsourcing facility may appeal, as set forth in 21 CFR 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 approximately 1 outsourcing facility (''no. of respondents'' in table 2, row 3) will submit an appeal of an FDA denial of a request for reconsideration. We estimate that approximately 1 appeal will be made by each facility containing the information described in the draft guidance (''total annual responses'' in table 2, row 3), and that it will take an outsourcing facility approximately 1 hour to prepare and submit each appeal under 21 CFR 10.75 (''average burden per response'' in table 2, row 3).

In the **Federal Register** of December 4, 2013 (78 FR 72899), FDA announced the availability of a draft guidance for industry entitled ''Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' In that notice, we estimated the burden under the PRA for submitting outsourcing facility registration information to FDA.

The total estimated reporting and recordkeeping burdens for this collection of information are 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	20	1	20	0.5	10
Request for Small Business Establishment Fee Reduction (Form FDA 3908)	10	1	10	25	250
Total					260

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN—REINSPECTION 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	5	1	5	0.5	2.5
Reconsideration request	2	1	2	1	2
Appeal request	1	1	1	1	1
Total					5.5

[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 records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Copy of small business designation letter	10	1	10	0.5	5

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

III. Comments

Interested persons may submit either electronic comments regarding the guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm166743.htm* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: March 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–06884 Filed 3–31–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at Vol. 79, FR 1882 dated January 10, 2014).

This notice reflects organizational changes to the Health Resources and Services Administration. Specifically, this notice updates the functional statement for the Healthcare Systems Bureau (RR), Office of Pharmacy Affairs (RR7).

Chapter RR—Healthcare Systems Bureau

Section RR–20, Functions

(1) Delete the functional statement for the Office of Pharmacy Affairs (RR7) and replace in its entirety.

Office of Pharmacy Affairs (RR7)

The Office of Pharmacy Affairs promotes access to clinical and cost effective pharmacy services to enable participating entities to stretch scarce federal resources in order to serve more patients, expand their services, or offer additional services. Specifically, the office: (1) Manages the 340B involvement of pharmaceutical manufacturers that participate in the Medicaid program, through Pharmaceutical Pricing Agreements; (2) maintains a publicly accessible database of participating covered entities, sites, and contract pharmacies; (3) publishes guidelines/regulations to assist in the understanding and participation in the 340B Program; (4) maintains a Prime Vendor Program to increase the value of the 340B Program; (5) provides technical assistance to Program stakeholders to support their appropriate and best use of the 340B Program; (6) fosters mutually productive