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

comment on the proposed 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[1]

Compounding outsourcing facility	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic Submission of Registration Information Using SPL Format	62	1	62	4.5	279
Waiver Request From Electronic Submission of Registration Information	1	1	1	1	1
Total					280

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

We estimate that approximately 62 outsourcing facilities (''number of respondents'' and ''total annual responses'' in table 1, row 1) will annually submit to FDA registration information using the SPL format as specified in the guidance, and that preparing and submitting this information will take approximately 4.5 hours per registrant (''average burden per response'' in table 1, row 1). We expect to receive no more than one waiver request from the electronic submission process annually (''number of respondents'' and ''total annual responses'' in table 1, row 2), and that each request should take approximately 1 hour to prepare and submit to us (''average burden per response'' in table 1, row 2).

Dated: October 10, 2017.

Anna K. Abram,

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

[FR Doc. 2017–22284 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–2017–N–5226]

Department of Health and Human Services, Supply Service Center et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Department of Health and Human Services, Supply Service Center et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications'' that appeared in the **Federal Register** of September 21, 2017 (82 FR 44185). The document announced the withdrawal of approval of 27 abbreviated new drug applications (ANDAs) from multiple applicants. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115, *lisa.granger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Thursday, September 21, 2017, in FR Doc. 2017–20107, on page 44185 the following correction is made:

On page 44185, in the second column, under the docket number FDA–2017–N–5526 is corrected to read ''FDA–2017–N–5226''.

Dated: October 11, 2017.

Anna K. Abram,

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

[FR Doc. 2017–22299 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–2017–D–5928]

Post-Complete Response Letter Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants Under the Generic Drug User Fee Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA.'' This guidance is intended to clarify the criteria for granting post-complete response letter (CRL) meeting requests and the scope of discussions for granted meeting requests. This guidance provides procedures that will promote well-managed post-CRL meetings and help ensure that such meetings are scheduled and conducted in accordance with the time frames set forth in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022 (GDUFA II Goals or Commitment Letter).

DATES: Submit either electronic or written comments on the draft guidance by December 15, 2017 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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