

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<sup>1</sup>

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

<sup>1</sup> 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.*

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## 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](mailto: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.*

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## 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