

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.*

[FR Doc. 2017-22284 Filed 10-13-17; 8:45 am]

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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

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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2017-D-5928 for “Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA; Draft Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 Dockets Management Staff. 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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Tamara R. Coley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 75, Rm. 1668, Silver Spring, MD 20903, 240-402-6903.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA.” The Generic Drug User Fee Amendments of 2017 (GDUFA II), reauthorizing generic drug user fees for Fiscal Years 2018–2022, was signed into law on August 18, 2017, to facilitate timely access to quality, affordable generic medicines. In accordance with the GDUFA II Commitment Letter<sup>1</sup> that accompanied the legislation, FDA agreed to certain review goals and procedures for the review of post-CRL meetings received on or after October 1, 2017.

The GDUFA II Commitment Letter adds time frames within which FDA will provide a scheduled date for, and will conduct, post-CRL meetings. Under GDUFA I, FDA committed to close out a certain number of teleconference

requests in fiscal year (FY) 2015 through FY 2017. In accordance with the GDUFA II Commitment Letter, FDA committed to schedule and conduct 90 percent of post-CRL meetings within prescribed time frames.

As described in the GDUFA II Commitment Letter, post-CRL meetings will be used by applicants “to seek clarification concerning deficiencies identified in a CRL.” Under GDUFA II, post-CRL meetings are available for both major and minor CRLs and for first and subsequent review cycles. FDA will grant any complete post-CRL meeting request that satisfies the criteria outlined in section IV. FDA will only grant post-CRL meeting requests that pose questions to clarify identified deficiencies. Other issues, including questions requiring further Agency review, disputes about classification of complete response amendments, or new information submitted by the applicant, will not be addressed in a post-CRL meeting.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

##### II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001.

##### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

<sup>1</sup> Available at <http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf>.

Dated: October 3, 2017.

**Anna K. Abram,**

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

[FR Doc. 2017-22288 Filed 10-13-17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0094]

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations**

**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 (the PRA).

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0562. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

#### **Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations**

*OMB Control Number 0910-0562—Extension*

The Food Quality Protection Act of 1996, which amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (the FD&C Act), established a new safety standard for pesticide residues in food, with an emphasis on protecting the health of infants and children. The Environmental Protection Agency (EPA) is responsible for regulating the use of pesticides (under FIFRA) and for establishing tolerances or exemptions from the requirement for tolerances for residues of pesticide chemicals in food commodities (under the FD&C Act). EPA may, for various reasons, *e.g.*, as part of a systematic review or in response to new information concerning the safety of a specific pesticide, reassess whether a tolerance for a pesticide residue continues to meet the safety standard in section 408 of the FD&C Act (21 U.S.C. 346a). When EPA determines that a pesticide's tolerance level does not meet that safety standard, the registration for the pesticide may be canceled under FIFRA for all or certain uses. In addition, the tolerances for that pesticide may be lowered or revoked for the corresponding food commodities. Under section 408(l)(2) of the FD&C Act, when the registration for a pesticide is canceled or modified due to, in whole or in part, dietary risks to humans posed by residues of that pesticide chemical on food, the effective date for the revocation of such tolerance (or exemption in some cases) must be no later than 180 days after the date such cancellation becomes effective or 180 days after the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

When EPA takes such actions, food derived from a commodity that was lawfully treated with the pesticide may not have cleared the channels of trade by the time the revocation or new tolerance level takes effect. The food could be found by FDA, the Agency that is responsible for monitoring pesticide residue levels and enforcing the pesticide tolerances in most foods (the U.S. Department of Agriculture has responsibility for monitoring residue levels and enforcing pesticide tolerances

in egg products and most meat and poultry products), to contain a residue of that pesticide that does not comply with the revoked or lowered tolerance. We would normally deem such food to be in violation of the law by virtue of it bearing an illegal pesticide residue. The food would be subject to FDA enforcement action as an "adulterated" food. However, the channels of trade provision of the FD&C Act addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical for which the tolerance has been revoked, suspended, or modified by EPA. The channels of trade provision (section 408 (l)(5) of the FD&C Act) states that food containing a residue of such a pesticide shall not be deemed "adulterated" by virtue of the residue, if the residue is within the former tolerance, and the responsible party can demonstrate to FDA's satisfaction that the residue is present as the result of an application of the pesticide at a time and in a manner that were lawful under FIFRA.

In the **Federal Register** of May 18, 2005 (70 FR 28544), we announced the availability of a guidance document entitled "Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations." The guidance represents FDA's current thinking on its planned enforcement approach to the channels of trade provision of the FD&C Act and how that provision relates to FDA-regulated products with residues of pesticide chemicals for which tolerances have been revoked, suspended, or modified by EPA under dietary risk considerations. The guidance can be found at the following link: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments/RegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/ucm077918.htm>. We anticipate that food bearing lawfully applied residues of pesticide chemicals that are the subject of future EPA action to revoke, suspend, or modify their tolerances, will remain in the channels of trade after the applicable tolerance is revoked, suspended, or modified. If we encounter food bearing a residue of a pesticide chemical for which the tolerance has been revoked, suspended, or modified, we intend to address the situation in accordance with provisions of the guidance. In general, we anticipate that the party responsible for food found to contain pesticide