

prevention of delayed graft function in kidney transplantation. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 under 21 CFR part 312 (investigational new drug application regulations) have been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0755. The collection of information under 21 CFR part 314, including the submission of information under subpart H (accelerated approval), has been approved under OMB control number 0910–0001. The collection of information under the guidance for industry entitled “Expedited Programs for Serious Conditions—Drugs and Biologics” (available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm358301.pdf>) has been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: July 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3077]

Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with FDA research in obtaining information from pharmacists and other management at outsourcing facilities as well as at related compounding businesses to support a comprehensive analysis of the outsourcing facility sector that will inform future FDA work in this area.

DATES: Submit either electronic or written comments on the collection of information by September 27, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. midnight Eastern Time at the end of September 27, 2019. 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):** 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–2019–N–3077 for “Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities.” 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 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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, 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 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.

Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

(OMB Control Number 0910–NEW)

This information collection supports Agency-sponsored research. Drug compounding is generally the practice of combining, mixing, or altering ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients when an approved drug is not medically appropriate, they also present a risk to patients. Compounded drugs are not FDA-approved. Therefore, they do not undergo premarket review by FDA for safety, effectiveness, and quality. Since compounded drugs are subject to a lower regulatory standard than approved drugs, Federal law places conditions on compounding that are designed to protect the public health.

The Drug Quality and Security Act of 2013 created “outsourcing facilities”—a new industry sector of drug compounders held to higher quality standards to protect patient health. Outsourcing facilities are intended to offer a more reliable supply of compounded drugs needed by hospitals, clinics, and other providers. Five years since its creation, this domestic industry is still relatively small and is experiencing growth and market challenges. In addition, FDA continues to find concerning quality and safety problems during inspections.

To help this industry meet its intended function, FDA intends to engage in several initiatives to address challenges and support compliance and advancement. One initiative includes conducting in-depth research to better understand challenges and opportunities encountered by the outsourcing facility sector in a number of different areas. These include: Operational barriers and opportunities related to the outsourcing facility market and business viability; knowledge and operational barriers and opportunities related to compliance with federal policies and good quality drug production; and barriers and

opportunities related to outsourcing facility interactions with FDA.

The results of this research will be used by FDA to develop a comprehensive understanding of the outsourcing facility sector, its challenges, and opportunities for advancement. The information will be essential to help identify knowledge and information gaps, operational barriers, and views on interactions with FDA. The research results will inform FDA’s future approaches to communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement.

Researchers will engage pharmacists, staff, and management from outsourcing facilities and similar compounding businesses. Researchers may use surveys, interviews, and focus groups to obtain information concerning challenges and opportunities encountered by outsourcing facilities. Within this context, the following questions or similar, related questions may be posed:

1. What financial and operational considerations inform outsourcing facility operational and business model decisions?
2. What factors impact the development of a sustainable outsourcing facility business?
3. What financial and operational considerations inform outsourcing facility product decisions?
4. Do outsourcing facilities understand the federal legislative and regulatory policies that apply to them? What, if any, knowledge gaps need to be addressed?
5. What challenges do outsourcing facilities face when implementing federal Current Good Manufacturing Practice (CGMP) requirements?
6. How do outsourcing facilities implement quality practices at their facilities?
7. How is CGMP and quality expertise developed by outsourcing facilities? How do they obtain this knowledge, and what training do they need?
8. What are the economic consequences of CGMP non-compliance/product failures for outsourcing facilities?
9. What are outsourcing facility management and staff views on current interactions with FDA? How do they want the interactions to change?
10. What are outsourcing facilities’ understanding of how to engage with FDA during and following an inspection?

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Surveys, focus groups, and interviews	300	2	600	1	600

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

We base our estimate of the average burden per response on review activities familiar to the Agency.

Dated: July 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-P-2559]

Determination That FORTAMET (Metformin Hydrochloride) Extended-Release Tablets, 500 Milligrams and 1 Gram, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that FORTAMET (metformin hydrochloride) extended-release tablets, 500 milligrams (mg) and 1 gram (g), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT:

Carlarease Hunter, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993-0002, 301-796-3702, *Carlarease.Hunter@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants

must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, are the subject of NDA 021574, held by Andrx Labs, LLC, and initially approved on April 27, 2004. FORTAMET is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, are currently listed in the “Discontinued Drug Product List” section of the Orange Book. Ajanta Pharma Limited submitted a citizen petition dated May 27, 2019 (Docket No. FDA-2019-P-2559), under 21 CFR 10.30, requesting that the Agency determine whether FORTAMET

(metformin hydrochloride) extended-release tablets, 500 mg and 1 g, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, from sale. We have also independently evaluated relevant literature and data for possible post marketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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