under the user fee provisions of the FD&C Act and the procedures for submitting requests for waivers, reductions, refunds, and requests for reconsiderations or appeals. The revised draft guidance also provides additional clarification on certain issues such as user fee exemptions for orphan drugs and FDA's current thinking on considerations relevant to eligibility for user fee waivers, reductions, and refunds under the applicable statutory provisions.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Prescription Drug User Fee Waivers, Reductions, and Refunds for Drug and Biological Products.'' 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 This draft guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (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.

The information collection of this draft guidance has been submitted for OMB renewal of approval under OMB control number 0910–0693. In addition, the collection of information associated with Form FDA 3397 has been previously approved under OMB control number 0910–0297. Collection of information associated with new drug application or biologics license applications have been previously approved under OMB control numbers 0910–0001 and 0910–0338, respectively. See section X of the draft guidance document.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,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

Dated: June 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–13295 Filed 6–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2014–D–2138]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Adverse Event Reporting for 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 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, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on adverse event reporting for outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by August 20, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 20, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of August 20, 2018. 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 2014–D–2138 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' 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: 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: 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, including each proposed extension of an existing 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.

Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0800—Extension

This information collection supports Agency implementation of the Drug Quality and Security Act (DQSA) (Pub. L. 113–54), which amended the FD&C Act by adding new section 503B (21 U.S.C. 353b).

This notice solicits comments on adverse event reporting for outsourcing facilities under section 503B of the FD&C Act.

Under section 503B(b), a compounder can register as an outsourcing facility with FDA. 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 certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and 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).

Under section 503B(b)(5), an outsourcing facility must submit adverse event reports to FDA in accordance with the content and format requirements established through guidance or regulation under 21 CFR 310.305 (or any successor regulations). Accordingly, we developed the document, ''Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act''.[1] The guidance explains electronic reporting of adverse events in accordance with § 310.305 with respect to outsourcing facilities.

Under § 310.305(c)(1), manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved NDA or ANDA, including, as set forth in the guidance, outsourcing facilities must submit to FDA adverse event reports within 15 calendar days of receiving the information and must submit follow-up reports within 15 calendar days of receipt of new information about the adverse event, or as requested by FDA. Outsourcing facilities must submit the adverse event report in an electronic format that FDA can process, review, and archive (collection of information is approved by OMB control number 0910–0291). A copy of the current labeling of the compounded drug product must be provided.

Under § 310.305(g), entities subject to the regulation must maintain for 10 years the records of all adverse events required to be reported under § 310.305. The outsourcing facility should also maintain records of its efforts to obtain the data elements described in the draft guidance for each adverse event report.

We estimate the burden of the information collection as follows:

[1] Available at: *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434188.pdf*.

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
Submission of adverse event reports including copy of labeling and other information as described in the guidance	55	1	55	1.1	61

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

TABLE 2—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
Records of adverse events, including records of efforts to obtain the data elements for each adverse event report	55	1	55	16	880

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

This is the first extension of the information collection and we have retained the currently approved burden estimate. Based on our review of Agency data, we estimate that annually 55 outsourcing facilities (''Number of Respondents'' and ''Total Annual Responses'' in table 1) will submit adverse event reports to FDA as specified in the guidance and that preparing and submitting this information will take approximately 1.1 hours per registrant (''Average Burden per Response'' in table 1). Likewise, we estimate that annually 55 outsourcing facilities (''Number of Recordkeepers'' in table 2) will maintain records of adverse events as specified in the guidance and that preparing and maintaining the records will take approximately 16 hours per registrant (''Average Burden per Recordkeeping'' in table 2).

Dated: June 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–13294 Filed 6–20–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2194]

Novartis Pharmaceuticals Corporation, et al.; Withdrawal of Approval of Five New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of five new drug applications (NDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of July 23, 2018.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 020831	Foradil Aerolizer (formoterol fumarate) Powder, 0.012 milligram (mg)/inhalation.	Novartis Pharmaceuticals Corp., One Health Pl., East Hanover, NJ 07936.
NDA 022504	Axiron (testosterone) Transdermal Metered Solution, 30 mg/1.5 milliliter (mL) actuation.	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
NDA 050585	Rocephin (ceftriaxone sodium) for Injection, equivalent to (EQ) 10 gram (g) base/vial, EQ 250 mg base/vial (IV/IM), EQ 500 mg base/vial (IV/IM), EQ 1 g base/vial (IV/IM), EQ 2 g base/vial (IV/IM), EQ 500 mg base/vial, N/A; N/A, 1% (Rocephin kit), EQ 1 g base/vial, N/A; N/A, 1% (Rocephin kit).	Hoffmann-La Roche, Inc., c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080.
NDA 050624	Rocephin (ceftriaxone sodium) with Dextrose in Plastic Container Injection, EQ 10 mg base/mL, EQ 20 mg base/mL, and EQ 40 mg base/mL.	Do.
NDA 202763	Testosterone Gel, 25 mg/2.5 g packet, 50 mg/5 g packet	ANI Pharmaceuticals, Inc., 210 Main St. West, Baudette, MN 56623.