

currently available data and information, the Agency believes that the potential problems associated with bacitracin for injection are sufficiently serious that the drug should be removed from the market.

In separate letters dated February 5, 2020, Akorn and Mylan requested that FDA withdraw approval of ANDAs 206719 and 090211 under § 314.150(d). Akorn and Mylan each waived their opportunity for a hearing. Additionally, in separate letters dated February 7, 2020, Pfizer, X-GEN, and Fresenius requested that FDA withdraw approval of ANDAs 060733, 064153, and 065116, respectively, under § 314.150(d). Pfizer, X-GEN, and Fresenius also waived their opportunity for a hearing. Additionally, Akorn stated that it has never launched this product since its approval; X-GEN stated that it no longer manufactures bacitracin for injection under ANDA 064153; and Mylan stated that its product has not been in commercial distribution since 2012.

Therefore, for the reasons discussed above, which the applicants do not dispute in their letters requesting withdrawal of approval under § 314.150(d), FDA's approval of ANDAs 206719, 090211, 060733, 064153, 065116, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of Akorn's bacitracin for injection (50,000 units/vial), Mylan's bacitracin for injection (50,000 units/vial), Pfizer's bacitracin for injection (10,000 units/vial and 50,000 units/vial), X-GEN's bacitracin for injection (50,000 units/vial), or Fresenius's bacitracin for injection (50,000 units/vial) into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: March 1, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-05105 Filed 3-11-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0279]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Marketing; Administrative Procedures, Policies, and Requirements

**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 information collection associated with prescription drug marketing under the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992.

**DATES:** Submit either electronic or written comments on the collection of information by May 11, 2021.

**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 May 11, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 11, 2021. 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-2011-N-0279 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Marketing; Administrative Procedures, Policies, and Requirements." 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, 240-402-7500.

- **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.govinfo.gov/content/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, 240-402-7500.

**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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), 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.

**Prescription Drug Marketing—21 CFR Part 203**

*OMB Control Number 0910-0435—Extension*

This information collection supports FDA regulations codified at part 203 (21 CFR part 203) implementing the Prescription Drug Marketing Act of 1987 (PDMA) and the Prescription Drug Amendments of 1992. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the PDMA, establishes requirements for the following:

- Reimportation of prescription drugs.
- The sale, purchase, or trade of or the offer to sell, purchase, or trade, prescription drugs that were purchased by hospitals or health care entities or donated to charitable organizations.
- The distribution of prescription drug samples by mail, common carrier, or another means of distribution.
- Applications for reimportation to provide emergency medical care.

- An appeal from an adverse decision by the district office.
- Drug sample storage and handling.
- Fulfillment houses, shipping and mailing services, comarketing agreements, and third-party recordkeeping.
- Donation of drug samples to charitable institutions.

The PDMA was enacted, in part, because insufficient safeguards existed over the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs. The PDMA is intended to ensure that drug products purchased by consumers are safe and effective, and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold.

The applicable regulations in part 203 include reporting and recordkeeping requirements intended to help achieve the following goals: (1) To ban the reimportation of prescription drugs produced in the United States, except when reimported by the manufacturer or under FDA authorization for emergency medical care; (2) to ban the sale, purchase, or trade, or the offer to sell, purchase, or trade, of any prescription drug sample; (3) to limit the distribution of drug samples to practitioners licensed or authorized to prescribe such drugs or to pharmacies of hospitals or other healthcare entities at the request of a licensed or authorized practitioner; (4) to require licensed or authorized practitioners to request prescription drug samples in writing; (5) to mandate storage, handling, and recordkeeping requirements for prescription drug samples; and (6) to prohibit, with certain exceptions, the sale, purchase, or trade, or the offer to sell, purchase, or trade, of prescription drugs that were purchased by hospitals or other healthcare entities or that were donated or supplied at a reduced price to a charitable organization.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR citation; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
203.11; reimportation applications .....	1	1	1	.5 (30 minutes) ...	<sup>2</sup> 1
203.37(a); falsification of records .....	140	21.4	3,000	.25 (15 minutes)	750
203.37(b); loss or theft of samples .....	140	178.57	25,000	.25 (15 minutes)	6,250
203.37(c); conviction of representatives .....	1	1	1	1 .....	1
203.37(d); contact person .....	20	1	20	.25 (15 minutes)	5
Total .....			28,022		7,007

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

<sup>2</sup> Rounded to the nearest whole number.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper <sup>2</sup>	Total annual records	Average burden per recordkeeping	Total hours
<b>Subpart C: Sales Restrictions</b>					
203.23(a) and (b); returns .....	2,200	71.9909	158,380	.25 (15 minutes)	39,595
203.23(c); documentation of storage of returns .....	2,200	71.9909	158,380	.08 (6 minutes) ...	12,670
<b>Subpart D: Samples</b>					
203.30–203.39; documentation regarding sample distributions.	140	202	28,280	~.07–.08 (~4–5 minutes).	2,121
Total .....			345,040		54,386

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

<sup>2</sup> Rounded to the nearest whole number.

Based on a review of Agency data, we assume 2,200 respondents may incur burden resulting from the information collection activity associated with the requirements in § 203.23(a) through (c). One hundred and forty pharmaceutical companies have submitted information to the Agency on drug sample distribution under part 203. Those same respondents also have recordkeeping requirements under part 203. Our estimate of the burden of the average burden per recordkeeping reflects a cumulative average to cover all applicable requirements. Since our last request for OMB approval, we have adjusted our estimate of the overall burden downward to reflect a decrease of 2,567,713 hours and 64,432,232 records annually. We attribute this adjustment to a more accurate reflection of the number of respondents to the information collection and clarification that burden attributable to requirements of the Drug Quality and Security Act are not included in this information collection.

Dated: March 9, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–05214 Filed 3–11–21; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2020–N–0026]

**Issuance of Priority Review Voucher; Rare Pediatric Disease Product**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that AMONDYS 45 (casimersen), manufactured by Sarepta Therapeutics Inc., meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:**

Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9856, email: [althea.cuff@fda.hhs.gov](mailto:althea.cuff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that AMONDYS 45 (casimersen) manufactured by Sarepta Therapeutics Inc., meets the criteria for a priority review voucher. AMONDYS 45 (casimersen) is indicated for the treatment of Duchenne Muscular Dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/>

*DevelopingProductsforRareDiseases Conditions/RarePediatricDiseasePriority VoucherProgram/default.htm*. For further information about AMONDYS 45 (casimersen), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: March 9, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–05208 Filed 3–11–21; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2020–N–2197]

**VistaPharm, Inc., et al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on December 11, 2020. The document announced the withdrawal of approval (as of January 11, 2021) of 10 abbreviated new drug applications (ANDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of the following two ANDAs after receiving a withdrawal request from VistaPharm, Inc., 7265 Ulmerton Rd., Largo, FL 33771: ANDA 040323, Prednisolone Syrup, 15 milligrams (mg)/5 milliliters (mL); and ANDA 075782, Valproic Acid Syrup, 250 mg/5 mL. Before FDA withdrew the approval of these ANDAs, VistaPharm, Inc., informed FDA that it did not want