

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper ²	Total annual records	Average burden per recordkeeping	Total hours
Subpart C: Sales Restrictions					
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
Subpart D: Samples					
203.30–203.39; documentation regarding sample distributions.	140	202	28,280	~.07–.08 (~4–5 minutes).	2,121
Total			345,040		54,386

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

² 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.

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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.

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.

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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