

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]

**BILLING CODE 4164-01-P**

**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]

**BILLING CODE 4164-01-P**

**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

the approval of the ANDAs withdrawn. Because VistaPharm, Inc., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 040323 and 075782 are still in effect.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, [Martha.Nguyen@fda.hhs.gov](mailto:Martha.Nguyen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Friday, December 11, 2020 (85 FR 80119), appearing in FR Doc. 2020-27303, the following correction is made:

On page 80119, in the table, the entries for ANDAs 040323 and 075782 are removed.

Dated: March 1, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-05103 Filed 3-11-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Population Sciences and Epidemiology.

*Date:* April 6, 2021.

*Time:* 9:00 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Lisa Steele, Ph.D., Scientific Review Officer, PSE IRG Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139,

MSC 7770, Bethesda, MD 20892, (301) 594-6594, [steeleln@csr.nih.gov](mailto:steeleln@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Population Sciences and Epidemiology: Additional Applications.

*Date:* April 6, 2021.

*Time:* 12:30 p.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Andrew Loudon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3137, Bethesda, MD 20817, (301) 435-1985, [loudenan@csr.nih.gov](mailto:loudenan@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Meeting Conflict: Glioma, Neuroinflammation and Autoimmunity and Neurovirology.

*Date:* April 7, 2021.

*Time:* 1:30 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, [edwardss@csr.nih.gov](mailto:edwardss@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 8, 2021.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2021-05163 Filed 3-11-21; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning

individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel Expanding Extramural Research Opportunities at the NIH Clinical Center (U01 Clinical Trial Optional).

*Date:* April 7, 2021.

*Time:* 11:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41B, Rockville, MD 20892 (Virtual Meeting).

*Contact Person:* Zhuqing (Charlie) Li, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41B, Rockville, MD 20852, (240) 669-5068, [zhuqing.li@nih.gov](mailto:zhuqing.li@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 8, 2021.

**Tyeshia M. Roberson,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2021-05161 Filed 3-11-21; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIDA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE ON DRUG ABUSE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NIDA.

*Date:* May 4, 2021.

*Time:* 9:00 a.m. to 5:00 p.m.