an approved drug from sale under § 314.81(b)(3)(iii).

We estimate 1,000 firms will expend 40 hours to prepare, review, and approve a standard operating procedure (SOP), for a total of 40,000 hours annually. Although we expect most respondents will have already prepared and implemented an SOP for the electronic submission of drug establishment registration and drug listing information, we retain an estimate for new firms that will do so, as recommended in the guidance.

Finally, we estimate 12,800 respondents are now subject to the reporting provisions introduced by the CARES Act under section 3112(e), and assume it will take 15 minutes to prepare and submit the requisite information, as shown in our 60-day notice. However, we have reduced this figure by 1,780 to 11,020 to reflect proposed reporting exemptions pertaining to: (1) Blood and blood components for transfusion and (2) cell and gene therapy products, where one lot treats a single patient. Consistent with section 510(j)(3)(B) of the FD&C Act, we have proposed to exempt these biological product categories from the reporting requirements in section 510(j)(3)(A) of the FD&C Act. If our proposed order is not finalized, we will adjust our estimate accordingly upon reevaluation of the information collection.

Overall, the information collection reflects an increase which we attribute to the new reporting required by section 510(j) of the FD&C Act, as amended by the CARES Act. We have otherwise retained the currently approved burden estimates for the provisions in part 207.

Dated: October 21, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23395 Filed 10–26–21; 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) 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 RETHYMIC (allogeneic processed thymus tissue-agdc), manufactured by Enzyvant Therapeutics, GmbH, meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

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), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that RETHYMIC (allogeneic processed thymus tissue-agdc), manufactured by Enzyvant Therapeutics, GmbH, meets the criteria for a priority review voucher. RETHYMIC (allogeneic processed thymus tissue-agdc) is indicated for immune reconstitution in pediatric patients with congenital athymia. RETHYMIC (allogeneic processed thymus tissue-agdc) is not indicated for the treatment of patients with severe combined immunodeficiency (SCID).

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/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs.* For further information about RETHYMIC (allogeneic processed thymus tissue-agdc), go to the Center for Biologics Evaluation and Research Cellular and Gene Therapy Products website at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

Dated: October 19, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23336 Filed 10–26–21; 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: In Toxicology, Pharmacology and Hepatology.

Date: December 2, 2021.

Time: 9:00 a.m. to 7:00 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: Santanu Banerjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2106, Bethesda, MD 20892, (301) 435–5947, *banerjees5@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Special Topics in Nephrology and Urology.

Date: December 2, 2021.

Time: 9:00 a.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: Stacey Nicole Williams, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–867–5309, *stacey.williams@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Genomics.

Date: December 2, 2021.

Time: 10:00 a.m. to 5:00 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: Jian Cao, M.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Room 4196, MSC 7844, Bethesda, MD 20892, (301) 827–5902, *caojn@csr.nih.gov.*