and has waived its opportunity for a hearing.

**DATES:** Approval is withdrawn as of May 2, 2022.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** On August 9, 2012, FDA approved NDA 202497 for MARQIBO (vinCRIStine sulfate LIPOSOME injection), 5 mg/5 mL, for the treatment of adult patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of MARQIBO (vinCRIStine sulfate LIPOSOME injection) for Ph-ALL included a required postmarketing clinical trial intended to verify the clinical benefit of MARQIBO (vinCRIStine sulfate LIPOSOME injection).

On September 24, 2021, FDA published the **Federal Register** notice ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments,'' announcing that MARQIBO (vinCRIStine sulfate LIPOSOME injection) would be discussed at an Oncologic Drug Advisory Committee Meeting (ODAC) scheduled for December 2, 2021 (86 FR 53067). On October 27, 2021, FDA met with Acrotech to discuss the planned ODAC meeting. At that meeting, the Agency recommended the applicant voluntarily request withdrawal of approval for MARQIBO (vinCRIStine sulfate LIPOSOME injection), 5 mg/5mL, due to the lack of verification of clinical benefit. The postmarketing trial required to verify clinical benefit had not been completed, and patient recruitment to fulfill the PMR appeared to be significantly challenging due to the treatment options that are currently available.

On November 19, 2021, Acrotech submitted a letter asking FDA to withdraw approval of NDA 202497 for MARQIBO (vinCRIStine sulfate LIPOSOME injection), 5 mg/5mL, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waiving its opportunity for a hearing. On November 23, 2021, FDA acknowledged Acrotech's request for withdrawal of approval of the NDA and waiver of its opportunity for hearing. FDA also cancelled the ODAC meeting scheduled for December 2, 2021, since Acrotech's withdrawal request made discussion at an advisory committee meeting moot.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 202497 for MARQIBO (vinCRIStine sulfate LIPOSOME injection), 5 mg/5mL, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of MARQIBO (vinCRIStine sulfate LIPOSOME injection) 5 mg/5mL, 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: April 26, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–09235 Filed 4–29–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–0895]**

### Issuance of Priority Review Voucher; Material Threat Medical Countermeasure 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 material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that INMAZEB (atoltivimab, maftivimab, and odesivimab-ebgn), manufactured by Regeneron Pharmaceuticals, Inc., meets the criteria for a material threat MCM priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Sadove, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8515, Fax: 301–796–8615, email: *EUA.OCET@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a), which was added by the Cures Act (Pub. L. 114–255), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that INMAZEB (atoltivimab, maftivimab, and odesivimab-ebgn), manufactured by Regeneron Pharmaceuticals, Inc., meets the criteria for a material threat MCM priority review voucher. INMAZEB was approved on October 14, 2020. mINMAZEB is a mixture of three monoclonal antibodies indicated for the treatment of infection caused by *Zaire ebolavirus* (Ebola virus) in adult and pediatric patients.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation.* For further information about INMAZEB (atoltivimab, maftivimab, and odesivimab-ebgn), go to the Drugs@FDA website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: April 26, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–09315 Filed 4–29–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0990–New]**

### Agency Information Collection Request; 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 1, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Evaluation of the National Hypertension Control Initiative (NHCI).

*Type of Collection:* (New) Agency Information Collection Request.

*OMB No.:* 0990–NEW–OS/Office of Minority Health (OMH).

*Abstract:* As part of the federal response to COVID–19, the U.S. Department of Health and Human Services (HHS) has funded a new initiative involving two cooperative agreements with the American Heart Association (AHA) to improve COVID–19-related health outcomes by addressing hypertension (high blood pressure) among racial and ethnic minority populations. The $32 million project from the HHS Office of Minority Health (OMH) and the Health Resources and Services Administration (HRSA) Bureau of Primary Health Care will support the implementation of the National Hypertension Control Initiative (NHCI), a national initiative to improve blood pressure control among the most at-risk populations, including racial and ethnic minorities.

The NHCI will support 350 participating HRSA-funded health centers by providing patient and provider education and training for effective hypertension control as well as integration of remote blood pressure monitoring technology into the treatment of hypertension for patients served by participating health centers. The project will also utilize the American Heart Association's targeted media campaigns and existing partnerships with community-based organizations (CBOs) to help reach Black, Latino, and other impacted communities with (i) culturally and linguistically appropriate messages, (ii) access to blood pressure screenings, and (iii) connection to health centers to encourage proper treatment and management of hypertension of screened individuals. This initiative serves to increase the number of adult patients with controlled hypertension and reduce the potential risk of COVID-related health outcomes.

AHA aims to conduct an evaluation to assess the feasibility of the implementation of each of the three NHCI strategies. The findings of this evaluation will inform the improvement and tailoring of AHA's communication approaches about the importance of and techniques for improving blood pressure control, including the benefits of accurately measuring, rapidly acting, and having a patient-focused approach to blood pressure control.

**Methodology**

The evaluation of the NHCI project will use a mixed methods design, integrating both quantitative and qualitative data collection and analyses. Three main goals of data collection will be to: (1) Track and monitor systems change implementation process information from Community Health Centers (CHCs) on a quarterly basis, (2) assess the capacity of NHCI partners to implement the NHCI project, their needs, the strengths and weaknesses of the systems change approach, and the feasibility of the implementation of the NHCI in their organizations and communities, and (3) assess the reach and success of NHCI project strategies implemented by partners.

Specifically, the AHA will engage in:

1. Primary Data Collection

a. *Qualtrics Survey.* Collecting participation and outcome data from CHCs and CBOs using an online survey administered using Qualtrics. This will be used during the first two quarterly data collection periods.

b. *DREaM.* Collecting participation and outcome data from CHCs and CBOs using an online Data Reporting, Evaluation, and Monitoring (DREaM) dashboard. This is the evolution of the Qualtrics survey and will be used after the first two quarterly data collection periods.

c. *Feasibility Assessments.* Engaging in qualitative and quantitative data collection using focus groups, interviews and questionnaires from CHCs and CBOs to assess the feasibility of various data collection and program implementation approaches.

d. *EmPOWERED to Serve.* Administering health lessons to community members via Community-based Organizations and assessing awareness, education, and referral outcomes.

2. Secondary Data Collection

a. *Social Needs Platforms.* CBOs and CHCs will be asked to use one of two publicly available social needs platforms (Find Help or Unite Us) and CHCs will be asked to use the Unite Us social needs platform to connect individuals receiving services at the CBOs to Community Health Centers (CHCs), and vice versa, to receive additional blood pressure-related services.

b. *Remote Patient Monitoring.* AHA will be partnering with Canary Telehealth to collect aggregate metrics from a subset of Community Health Centers (CHCs).

c. *Blood Pressure Control Metrics via Electronic Health Records.* AHA will be partnering with external research partners to obtain reports of aggregated blood pressure control metrics from NHCI CHCs to inform clinical decision making, clinical quality improvement, and clinical outcomes.

ANNUALIZED BURDEN HOUR TABLE

| Type of respondent | Number of respondents | Number responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|
| CHCs: Qualtrics survey (4 quarters) | 350 | 2 | 1.5 | 1,050 |
| CBOs: Qualtrics survey (4 quarters) | 16 | 2 | 1.5 | 192 |
| CHCs: Training on data entry into DREaM | 350 | 1 | 1 | 350 |

ANNUALIZED BURDEN HOUR TABLE—Continued

| Type of respondent | Number of respondents | Number responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|
| CBOs: Training on data entry into DREaM | 16 | 1 | 1 | 16 |
| CHCs: Quarterly data entry in DREaM | 350 | 2 | 1.5 | 1,050 |
| CBOs: Quarterly data entry into DREaM | 16 | 2 | 30/60 | 16 |
| CHCs: Feasibility assessment focus groups (3 times a year) | 16 | 3 | 1.5 | 72 |
| CBOs: Feasibility assessment focus groups (3 times a year) | 16 | 3 | 1.5 | 72 |
| Individual Consumers: ETS health lesson learning questionnaires | 3,120 | 1 | 10/60 | 1,872 |
| CHCs: Social Needs Platforms Readiness Assessment | 350 | 1 | 15/60 | 87.5 |
| CBOs: Social Needs Platforms Readiness Assessment | 16 | 1 | 15/60 | 4 |
| Individual Consumers: Social Needs Platform Participation | 10,000 | 1 | 10/60 | 1,666 |
| Management Occupation: RPM provider data delivery | 1 | 4 | 1 | 4 |
| CBOs: Remote Patient Monitoring (RPM) | 5 | 1 | 1 | 5 |
| Individual Consumers: Remote Patient Monitoring (RPM) | 2,750 | 1 | 1 | 2,750 |
| Blood Pressure Control Metrics via Electronic Health Records | 0 | 0 | 0 | 0 |
| Total | | | | 8,141 |

**Sherrette A. Funn,**

*Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.*

[FR Doc. 2022–09318 Filed 4–29–22; 8:45 am]

**BILLING CODE 4150–29–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:* Healthcare Delivery and Methodologies Integrated Review Group; Science of Implementation in Health and Healthcare Study Section.

*Date:* June 8–9, 2022.

*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:* Wenjuan Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 480–8667, *wangw22@mail.nih.gov.*

*Name of Committee:* Infectious Diseases and Immunology A Integrated Review Group; Innate Immunity and Inflammation Study Section.

*Date:* June 16–17, 2022.

*Time:* 9:30 a.m. to 8:30 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:* Shahrooz Vahedi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 810G, Bethesda, MD 20892, (301) 496–9322, *vahedis@mail.nih.gov.*

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Cellular and Molecular Biology of Neurodegeneration Study Section.

*Date:* June 23–24, 2022.

*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:* Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7850, Bethesda, MD 20892, 301–435–1203, *laurent.taupenot@nih.gov.*

*Name of Committee:* Bioengineering Sciences & Technologies Integrated Review Group; Biomaterials and Biointerfaces Study Section.

*Date:* June 23–24, 2022.

*Time:* 9:30 a.m. to 8:30 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:* Shivani Sharma, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 507–7661, *shivani.sharma@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Topics in Bacterial Pathogenesis.

*Date:* June 23–24, 2022.

*Time:* 10:00 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:* Susan Daum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, Bethesda, MD 20892, 301–827–7233, *susan.boyle-vavra@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: April 26, 2022.

**David W. Freeman,**

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

[FR Doc. 2022–09328 Filed 4–29–22; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Aging; 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