notice, (Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements) as authorized under § 488.8, we will continue ongoing review of TJC's hospital survey. In keeping with CMS's initiative to increase AO oversight broadly, and ensure that our requested revisions by TJC are completed, CMS expects more frequent review of TJC's activities in the future.

VI. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 27, 2022.

Lynette Wilson,

Federal Register Liaison, Center for Medicare & Medicaid Services.

[FR Doc. 2022–09361 Filed 4–29–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–3427]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by 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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease Application and Survey and Certification Report; *Use:* The Form CMS–3427 is required for each new ESRD facility seeking initial certification and for each existing facility seeking recertification, relocation, expansion/change of service(s), or change of ownership. The form is also used for information collection purposes related to a complaint survey of an ESRD facility. The Form CMS–3427 information is currently collected on paper as a manual option or may be completed in an online fillable format based on facility preference. This online form is a step in the direction towards electronic submission. *Form Number:* CMS–3427 (OMB control number: 0938–0360); *Frequency:* Every three years; *Affected Public:* Private sector (Business or other for-profit and Not-for profit institutions); *Number of Respondents:* 7,883; *Total Annual Responses:* 2,601; *Total Annual Hours:* 866. (For policy questions regarding this collection contact Jennifer Milby at 410–786–8828).

Dated: April 27, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–09388 Filed 4–29–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0354]

Acrotech Biopharma LLC; Withdrawal of Approval of New Drug Application for MARQIBO (VinCRIStine Sulfate LIPOSOME Injection), 5 milligrams/5 milliliters

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of new drug application (NDA) for MARQIBO (vinCRIStine sulfate LIPOSOME injection), 5 milligrams (mg)/5 milliliters (mL), held by Acrotech Biopharma LLC (Acrotech), 29 Princeton Hightstown Rd., East Windsor, NJ 08520. Acrotech has voluntarily requested that FDA withdraw approval of this application

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.