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DATES: Approval is withdrawn as of May 2, 2022.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

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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.