Dated: October 8, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–23646 Filed 10–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0335]

Revocation of Emergency Use of a Biological Product During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Janssen Biotech, Inc. (Janssen), for the Janssen COVID–19 Vaccine. FDA revoked the Authorization on June 1, 2023, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

DATES: The Authorization is revoked as of June 1, 2023.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On February 27, 2021, FDA issued an Authorization (EUA 27205) to Janssen for the Janssen COVID–19 Vaccine, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on May 27, 2021 (86 FR 28608), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorization were made available on FDA's website. The authorization of a biological product for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Request

In a request received by FDA on May 22, 2023, Janssen requested withdrawal of, and on June 1, 2023, FDA revoked, the Authorization for the Janssen COVID–19 Vaccine. Janssen notified FDA that the last lots of the Janssen COVID–19 Vaccine purchased by the U.S. Government have expired, that there is no demand for new lots of the Janssen COVID–19 Vaccine in the United States, and that it does not intend to update the strain composition of this vaccine to address emerging variants. Based on FDA's understanding that Janssen does not intend to offer the Janssen COVID–19 Vaccine in the United States under the EUA anymore and Janssen's request that FDA revoke the EUA for the Janssen COVID–19 Vaccine, FDA has determined that it is appropriate to revoke this Authorization to protect the public health or safety.

III. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA for the Janssen COVID–19 Vaccine. Although FDA revoked the Authorization for the Janssen COVID–19 Vaccine on June 1, 2023, as was publicly announced on the Agency's website, publication of notice of this revocation in the **Federal Register** was inadvertently delayed. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

IV. Electronic Access

An electronic version of this document and the full text of the Authorizations and revocation are available on the internet at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

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U.S. FOOD & DRUG ADMINISTRATION

June 1, 2023

Janssen Biotech, Inc.
Attention: Ms. Ruta Walawalkar
920 Route 202
Raritan, NJ 08869

Re: Revocation of EUA 27205 - Janssen COVID-19 Vaccine

Dear Ms. Walawalkar:

This letter is in response to the request from Janssen Biotech, Inc. received on May 22, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Janssen COVID-19 Vaccine issued on February 27, 2021, as subsequently amended. Janssen Biotech, Inc has informed the FDA that the last lots of the Janssen COVID-19 Vaccine purchased by the United States Government have expired, that there is no demand for new lots of the Janssen COVID-19 Vaccine in the United States, and that Janssen Biotech, Inc does not intend to update the strain composition of this vaccine to address emerging variants.

The authorization of a biological product for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because FDA understands that Janssen Biotech, Inc. no longer intends to offer the Janssen COVID-19 Vaccine in the United States under the EUA and because Janssen Biotech, Inc. has requested that FDA withdraw the EUA for the Janssen COVID-19 Vaccine, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 27205 for the Janssen COVID-19 Vaccine, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Janssen COVID-19 Vaccine is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the Federal Register, pursuant to section 564(h)(1) of the Act.

Sincerely,

Peter W. Marks -S

Digitally signed by Peter W. Marks -S
Date: 2023.06.01 14:08:52 -04'00'

Peter Marks, M.D, Ph.D.
Director
Center for Biologics Evaluation and Research

Dated: September 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–23637 Filed 10–11–24; 8:45 am]

BILLING CODE 4164–01–C

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; AQNEURSA (Levacetylleucine)

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 AQNEURSA (levacetylleucine), approved on September 24, 2024, manufactured by IntraBio Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394.

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 AQNEURSA (levacetylleucine), manufactured by IntraBio Inc., meets the criteria for a priority review voucher. AQNEURSA (levacetylleucine) is indicated for the treatment of neurological manifestations of Niemann-Pick disease type C in adults and pediatric patients weighing ≥15 kg.

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/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about AQNEURSA (levacetylleucine), go to the ''Drugs@FDA'' website at *http://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: October 8, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–23712 Filed 10–11–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 89 FR 19832 dated March 20, 2024) to reorganize sections of the Maternal and Child Health Bureau (MCHB).

This reorganization updates and/or realigns functions, including delegations of authority for MCHB (RM).

Chapter RM—Maternal and Child Health Bureau (RM)

Section RM.10 Organization

Establish the Office of Strategy, Innovation, and External Affairs and the Division of Women's Health.

Following this realignment, MCHB includes the following components:

- Office of the Associate Administrator (RM),
- Office of Policy and Planning (RMA),
- Office of Strategy, Innovation, and External Affairs (RMB),
- Office of Operations and Management (RM1),
- Division of Services for Children with Special Health Needs (RM2),
- Division of Child, Adolescent, and Family (RM3),
- Division of Maternal and Child Health Workforce Development (RM4),
- Division of Healthy Start and Perinatal Services (RM5),
- Division of State and Community Health (RM6),
- Division of Home Visiting and Early Childhood Systems (RM8),
- Office of Epidemiology and Research (RM9), and
- Division of Women's Health (RMC).

Section RM.20 Function

Update the functional statements for the Office of the Associate Administrator, Office of Policy and Planning, Division of Healthy Start and Perinatal Services, and Division of Home Visiting and Early Childhood Systems and add the functional statement for the Office of Strategy, Innovation, and External Affairs and Division of Women's Health:

Office of the Associate Administrator (RM)

The Office of the Associate Administrator provides national leadership and policy direction for MCHB programs. These programs are designed to improve the health of women of childbearing age, infants, children, adolescents and their families, children with special health needs, and persons with hemophilia. Specifically, the Office: (1) coordinates the planning, development, implementation, and evaluation of MCHB's programs and activities; (2) facilitates effective, collaborative relationships with other health and related programs; (3) establishes program mission, goals, objectives, and policy with broad Administration guidelines; (4) arranges and provides technical assistance to ensure that grantees meet program expectations; (5) serves as principal contact point across HRSA, HHS, and other agencies on matters concerning the health status of America's mothers and children; and (6) provides information and reports on MCHB's programs to Congress, other federal agencies, the public, and other stakeholders.

Office of Policy and Planning (RMA)

The Office of Policy and Planning serves as MCHB's focal point for the development of MCHB policy and program planning. Specifically, the Office: (1) supports the Office of the Associate Administrator in identifying, planning, and implementing policy and program priorities across MCHB; (2) advises and assists in the development, coordination, and management of program and policy documents and responses to departmental and HRSA initiatives; and (3) coordinates with other components within HRSA, HHS, federal agencies, state and local governments, and other public and private organizations on issues affecting MCHB programs and policies.

Office of Strategy, Innovation, and External Affairs (RMB)

The Office of Strategy, Innovation, and External Affairs serves as MCHB's focal point for strategic planning,