

Dated: September 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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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; 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/RarePediatricDiseasePriority VoucherProgram/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,