

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  $\geq 15$  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,

communications, external engagement, and program development. Specifically, the Office works closely with the Office of the Associate Administrator to develop strategic plans, facilitate program alignment, and support special initiatives.

#### **Division of Healthy Start and Perinatal Services (RM5)**

The Division of Healthy Start and Perinatal Services provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focused on maternal, infant, family, and women's health for targeted populations, especially for those at high-risk for poor health and health outcomes. Specifically, the Division: (1) administers local, state, and national programs on perinatal and women's health, with an emphasis on infant mortality reduction and eliminating disparities in infant, maternal, and women's health outcomes before and after pregnancy; (2) develops policy and provides technical assistance, national resource development and dissemination, and workforce development to address national trends in maternal, infant, family, and women's health status and gaps in evidence-based healthcare services for these populations as well as Division programs; (3) administers funds and other resources for grants, contracts, and cooperative agreements; (4) coordinates with MCHB, agency, departmental, and intradepartmental initiatives in promoting the Division's program objectives and the mission of MCHB; (5) coordinates the Advisory Committee on Infant and Maternal Mortality; (6) liaises with public, private, professional, and non-governmental organizations for Division programs; (7) disseminates information on Division programs to local, state, and national audiences; (8) participates in strategic and policy planning, health services research and evaluation, regulatory activities, and fiscal strategic planning, administration, and analysis relating to Division programs; and (9) provides technical assistance and support to central and regional office staff of MCHB, HRSA, HHS, and other federal agencies.

#### **Division of Home Visiting and Early Childhood Systems (RM8)**

The Division of Home Visiting and Early Childhood Systems plans, develops, implements, oversees, monitors, and evaluates national programs, including the Maternal, Infant, and Early Childhood Home Visiting Program and a portfolio of early childhood systems programs.

Specifically, the Division: (1) provides leadership and coordination of federal, regional, state, local, and non-governmental efforts to promote the health and well-being of pregnant women, infants, young children and their families; (2) develops, analyzes, and/or disseminates policies, standards, guidelines, research, and evaluation information for the various Division programs; (3) establishes and maintains cooperative relationships within HRSA, with other federal agencies, and with other relevant public and private organizations to implement programs to improve maternal and child health outcomes, develop and improve comprehensive coordinated early childhood systems, conduct research and evaluation, and advance educational and training programs for the early childhood workforce; (4) administers and manages a program of interagency agreements, cooperative agreements, grants, and contracts that will enhance service delivery and systems building; and (5) provides technical assistance and engagement to state and local health personnel, other federal agencies, and other stakeholders on maternal health, early childhood health and development, and comprehensive and coordinated systems of care.

#### **Division of Women's Health (RMC)**

The Division of Women's Health provides national leadership in policy, planning, programming, outreach, and education to improve the health, wellness, and safety of women across the lifespan. Specifically the Division: (1) provides leadership, technical assistance, and support to improve health outcomes for women; (2) engages with health professionals and other stakeholders to identify and disseminate the latest evidence and best practices in women's health; (3) establishes short-range and long-range goals, plans, leads, and administers activities that improve women's health; (4) enhances the health care infrastructure and service delivery system by supporting innovative programs throughout the lifespan for women as well as for children and families; and (5) works to improve prevention, early identification, treatment, and referral for health services for women and their families.

#### **Section RM.30 Delegation of Authority**

All delegations of authority and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, if allowed,

provided they are consistent with this reorganization.

This reorganization is effective upon date of signature.

(Authority: 44 U.S.C. 3101)

**Carole Johnson,**  
Administrator.

[FR Doc. 2024-23783 Filed 10-11-24; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Office of the Secretary**

#### **Findings of Research Misconduct**

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

**ACTION:** Notice.

**SUMMARY:** Findings of research misconduct have been made against Bret Rutherford, M.D. (Respondent), who was formerly a Research Psychiatrist, New York State Psychiatric Institute (NYSPI). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grants R01 MH102293 and R61/R33 MH110029. The administrative actions, including debarment for a period of three (3) years followed by supervision for a period of three (3) years, were implemented beginning on September 27, 2024, and are detailed below.

**FOR FURTHER INFORMATION CONTACT:** Sheila Garrity, JD, MPH, MBA, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453-8200.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

*Bret Rutherford, M.D., New York State Psychiatric Institute (NYSPI):* Based on the report of an investigation conducted by NYSPI and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Bret Rutherford (Respondent), former Research Psychiatrist, NYSPI, engaged in research misconduct in research supported by PHS funds, specifically, NIMH, NIH, grants R01 MH102293 and R61/R33 MH110029.

ORI found that Respondent engaged in research misconduct by recklessly falsely reporting that all human research subjects met the inclusion/exclusion criteria for late-life depression studies in five (5) published papers, thus affecting the reported clinical research methods and results including demographics,