

available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Chris Wheeler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-0151; or Anne Taylor, 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

FDA is announcing the availability of a guidance for industry entitled “Human Prescription Drug and

Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—‘Dose Banding.’” This guidance provides recommendations for incorporating dose banding information into the labeling of an injectable drug product that is seeking approval through a new drug application submitted under section 505(b) of the FD&C Act (21 U.S.C. 355(b)), a biologics license application submitted under section 351(a) of the PHS Act (42 U.S.C. 262(a)), or a supplement to one of these approved applications. The recommendations and examples in this guidance are relevant to situations in which an applicant (1) proposes to develop ready-to-use containers with a range of different strengths for an injectable drug product and (2) seeks to incorporate dose banding information into the prescribing information based on dosing information of a previously approved drug product that is based on weight or BSA.

This guidance finalizes the draft guidance entitled “Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—‘Dose Banding.’” issued on July 21, 2022 (87 FR 43533). FDA considered comments received on the draft guidance as it developed the final guidance. Changes from the draft guidance are primarily intended to improve clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—‘Dose Banding.’” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by Office of Management Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 201 have been approved

under OMB control number 0910-0572; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-21558 Filed 9-29-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Regional Pediatric Pandemic Network

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Announcing supplemental funding for Regional Pediatric Pandemic Network award recipients in Maryland and Ohio.

SUMMARY: HRSA provided additional award funds to the two Regional Pediatric Pandemic Network (RPPN) Program recipients in Maryland and Ohio with periods of performance ending in fiscal year 2024.

FOR FURTHER INFORMATION CONTACT: Sara Kinsman, MD, Director, Division of Child, Adolescent and Family Health, Maternal and Child Bureau, Health Resources and Services Administration, at SKinsman@hrsa.gov and 301-443-2250.

SUPPLEMENTARY INFORMATION:

Intended Recipient(s) of the Award: The two award recipients of the HRSA Regional Pediatric Pandemic Network Program are Children’s National Medical Center in Maryland, and University Hospitals Cleveland Medical Center in Ohio, as listed in Table 1.

TABLE 1—RECIPIENTS AND SUPPLEMENT AWARD AMOUNTS

Grant No.	Award recipient name	City, state	Award amount
U1IMC45814	Children's National Medical Center	MD	\$400,000
U1IMC43532	University Hospitals Cleveland Medical Center	OH	400,000

Amount of Non-Competitive

Award(s): Two awards at \$400,000 per grant recipient totaling \$800,000.

Project Period: September 1, 2023, to August 31, 2024.

Assistance Listing (CFDA) Number: 93.110.

Award Instrument: Supplement for RPPN support services.

Justification: Approximately \$400,000 in supplemental funding has been awarded to each RPPN cooperative agreement recipient to increase activities to coordinate among the nation's pediatric hospitals and their communities to prepare for and respond to global health threats and coordinate research-informed responses to future pandemics. Projects approved by HRSA under this supplement are to be performed from the date of award through August 31, 2024.

Carole Johnson,

Administrator.

[FR Doc. 2023–21670 Filed 9–29–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Infant and Maternal Mortality

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Department of Health and Human Services is giving notice that the Advisory Committee on Infant and Maternal Mortality (ACIMM or Committee) is renewed. The effective date of the charter renewal is September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N84, Rockville, Maryland 20857; 301–443–0543; or VLee1@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACIMM is authorized by section 222 of the Public

Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92–463, as amended (5 U.S.C. 10), which sets forth standards for the formation and use of Advisory Committees. ACIMM advises the Secretary of Health and Human Services on department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. The Committee provides advice on how best to coordinate Federal, State, local, Tribal, and Territorial governmental efforts designed to improve infant mortality, related adverse birth outcomes, and maternal health, as well as influence similar efforts in the private and voluntary sectors. The Committee provides guidance and recommendations on the policies, programs, and resources required to address the disparities and inequities in infant mortality, related adverse birth outcomes and maternal health outcomes, including maternal mortality and severe maternal morbidity. With its focus on underlying causes of the disparities and inequities seen in birth outcomes for women and infants, the Committee advises the Secretary of Health and Human Services on the health, social, economic, and environmental factors contributing to the inequities and proposes structural, policy and/or systems level changes.

The charter renewal for ACIMM was approved on September 8, 2023. The filing date is September 30, 2023. Renewal of the ACIMM charter gives authorization for the committee to operate until September 30, 2025.

A copy of the ACIMM charter is available on the ACIMM website at <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for

the FACA database is <http://www.facadatabase.gov/>.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–21716 Filed 9–29–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group, Therapeutic Development and Preclinical Studies Study Section.

Date: October 25–26, 2023.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Richard D Schneiderman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, Bethesda, MD 20817, 301–402–3995, richard.schneiderman@nih.gov.

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group, Cellular and Molecular Technologies Study Section.

Date: October 25–26, 2023.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Tatiana V Cohen, Ph.D., Scientific Review Officer, Center for