SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Severely Debilitating or Life-Threatening Hematologic Disorders: Nonclinical Development of Pharmaceuticals.'' The purpose of this guidance is to provide information to assist sponsors in the design of an appropriate program of nonclinical studies for the development of pharmaceuticals used to treat patients with SDLTHDs. While FDA has guidance for oncology indications (most of which are considered severely debilitating or life-threatening diseases) and for rare diseases (which include some SDLTHD conditions), FDA has no guidance to facilitate nonclinical development specifically for pharmaceuticals used to treat nononcology patients with SDLTHDs.

The SDLTHDs include conditions in which life expectancy is short or quality of life is greatly diminished despite available therapies. FDA has defined life-threatening and severely debilitating diseases in regulations (21 CFR 312.81). A streamlined approach to drug development is necessary to allow patients with SDLTHDs earlier and continued access to new and potentially effective therapies. This guidance, when finalized, is expected to reduce the use of animals in accordance with the 3R (refine/reduce/replace) principles and allow faster and continuous access to pharmaceuticals for SDLTHDs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on nonclinical development of pharmaceuticals for severely debilitating or life-threatening hematologic disorders. 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: April 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–08548 Filed 4–23–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Statewide Needs Assessment Update

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit a Supplemental Information Request (SIR), described below, to the Office of Management and Budget (OMB). Prior to submitting the SIR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the SIR.

DATES: Comments on this SIR should be received no later than June 25, 2018.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Needs Assessment Update

OMB No.: 0906–XXXX, New.

Abstract: HRSA is requesting approval to collect updated statewide needs assessments from Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program awardees. The previous statewide needs assessment that was approved under OMB control number 0915–0333 has been discontinued. Eligible entities that are states, the District of Columbia, and non-profit organizations will submit statewide needs assessment updates in response to a forthcoming SIR.

The MIECHV Program, authorized by section 511 of the Social Security Act, 42 U.S.C. 711, and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, territories, and tribal entities, and nonprofit organizations, in certain circumstances, are eligible to receive funding through MIECHV and have the flexibility, within the parameters of the authorizing statute, to tailor the program to serve the specific needs of their communities.

The statewide needs assessment is a critical and foundational resource that assists awardees in identifying and understanding how to meet the needs of eligible families living in at-risk communities in their states.

Need and Proposed Use of the Information: Congress, through enactment of the Social Security Act, Title V, Section 511 (42 U.S.C. 711), as amended, established the MIECHV Program. The MIECHV Program is designed to: (1) Strengthen and improve the programs and activities carried out under Title V of the Social Security Act; (2) improve coordination of services for at risk communities; and (3) identify and provide comprehensive services to improve outcomes for families who reside in at risk communities. Section 50603 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) amended section 511(b)(1) of the Social Security Act, and requires that states review and update their statewide needs assessments (which may be separate from, but in coordination with, the Title V statewide needs assessment) no later than October 1, 2020, as a condition of receiving payments from Title V Block Grant allotments.

In response to the forthcoming SIR, state and territory awardees will be required to submit an updated statewide needs assessment that identifies all of the following information, as required by the MIECHV authorizing statute:

(1) Communities with concentrations of (a) premature birth, low-birth weight infants, and infant mortality, including infant death due to neglect, or other indicators of at-risk prenatal, maternal, newborn, or child health; (b) poverty; (c) crime; (d) domestic violence; (e) high rates of high-school drop-outs; (f) substance abuse; (g) unemployment; or (h) child maltreatment.

(2) The quality and capacity of existing programs or initiatives for early

childhood home visitation in the state including: the number and types of individuals and families who are receiving services under such programs or initiatives; the gaps in early childhood home visitation in the state; and the extent to which such programs or initiatives are meeting the needs of eligible families.

(3) The state's capacity for providing substance abuse treatment and counseling services to individuals and families in need of such treatment or services.

The forthcoming SIR will provide further guidance to states in updating their statewide needs assessments and submitting the required information to HRSA. States that have elected not to apply for or be awarded MIECHV funds are encouraged to work with nonprofit organizations that have received awards to provide MIECHV services within the state and indicate whether they will submit their needs assessments directly or through the nonprofit organization awardee. HRSA, states, and nonprofits providing MIECHV services within states will use the information collected through the needs assessment update to reaffirm the provision of MIECHV home visiting services in at-risk communities. The information will also be used to support program planning, improvement, and decision-making. The needs assessment update is not intended to disrupt current services or negatively impact communities that have benefited from home visiting programs, nor is the intent of the update to require awardees to shift resources away from at-risk communities they currently serve.

Likely Respondents: MIECHV Program Awardees that are states, territories, and, where applicable, nonprofit organizations providing services within states.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions and supporting materials; to collect and analyze data; engage with stakeholders and coordinate with state level partners; and to draft and submit the report. The table below summarizes the total annual burden hours estimated for this SIR.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Instrument	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
Maternal, Infant, and Early Childhood Home Visiting Program Statewide Needs Assessment Update	56	1	56	95.57	5,352
Total	56		56		5,352

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–08539 Filed 4–23–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings of the NHLBI Special Emphasis Panel.

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 contract proposals and 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 contract proposals and grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; National Gene Vector Biorepository Contract Review.

Date: May 14, 2018.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Charles Joyce, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892–7924, 301–827–7939, *cjoyce@nhlbi.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Acute Lung Injury Program Project Review.

Date: May 15, 2018.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton BWI (Baltimore), 1100 Old Elkridge Landing Road, Baltimore, MD 21090.

Contact Person: Shelley S. Sehnert, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892–7924, 301–435–0303, *ssehnert@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 18, 2018.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–08443 Filed 4–23–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Cancellation Notice of Meeting

Notice is hereby given of the cancellation of the National Cancer Institute Special Emphasis Panel, May 21, 2018, 5:00 p.m. to May 22, 2018, 5:00 p.m., Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Linden Oak, Rockville, MD, 20852 which was published in the **Federal Register** on April 6, 2018, 83 FR 14869.