adherence with risk management guidance.

Public comments are requested, including those expressing support or with specific suggestions to improve the Research plan. A copy of the draft Research plan is available at *https://www.regulations.gov* (see Docket Number CDC–2018–0038).

Dated: April 19, 2018.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–08472 Filed 4–23–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1328]

Severely Debilitating or Life-Threatening Hematologic Disorders: Nonclinical Development of Pharmaceuticals; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Severely Debilitating or Life-Threatening Hematologic Disorders: Nonclinical Development of Pharmaceuticals.''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 severely debilitating or life-threatening hematologic disorders (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. A streamlined approach to drug development is necessary to allow patients with SDLTHDs earlier and continued access to new and potentially effective therapies.

DATES: Submit either electronic or written comments on the draft guidance by June 25, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1328 for ''Severely Debilitating or Life-Threatening Hematologic Disorders: Nonclinical Development of Pharmaceuticals; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions–To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly 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.gpo.gov/fdsys/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.

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

Submit written requests for single copies of the draft 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: John Leighton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2204, Silver Spring, MD 20993–0002, 301–796–0750; or Haleh Saber, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2117, Silver Spring, MD 20993–0002, 301–796–0750.

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