

2020–D–1294 for “Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products.” 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.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.

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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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; or to 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Patricia Keegan, Center for Drug Evaluation and Research, Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 22, Rm. 2322, Silver Spring, MD 20993, 301–796–1387; or Stephen Ripley, 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 draft guidance for industry entitled “Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products.” When finalized, this guidance will describe FDA’s current recommendations about endotoxin limits in investigational oncology drugs and biological products. It looks at a risk-based approach of weighing the potential risks of not evaluating endotoxin levels in all components of a multidrug regimen against the potential benefits to patients with serious and life-threatening diseases. It is limited to anticancer drugs administered parenterally (except for intraocular administration) to treat serious and life-threatening cancers based on histology or stage of disease.

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 “Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products.” 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

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction

Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the draft 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>, or <https://www.regulations.gov>.

Dated: July 22, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16340 Filed 7–28–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information on Innovative Programs To Reconnect Youth to Education and Employment and Promote Self-Sufficiency

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: HHS issues this Request for Information (RFI) in order to seek information about programs that provide services to help young people, ages 16 to 24, advance on education and employment pathways. This project is focused on the population of young people who are out of work and/or out of school, particularly those from lower income families and communities, sometimes called disconnected or opportunity youth. The information gathered will result in a public compendium that profiles selected programs operating in this area, particularly innovative programs.

DATES: Submit written comments at the address provided below no later than September 28, 2020.

ADDRESSES: Written comments should be submitted to ReconnectingYouthRFI@hhs.gov. HHS encourages the early submission of comments.

FOR FURTHER INFORMATION CONTACT: Lisa Trivits on the Reconnecting Youth team at ReconnectingYouthRFI@hhs.gov or 202–205–9256.

SUPPLEMENTARY INFORMATION: *Invitation to Comment:* HHS invites comments

responding to the questions included in this notice. To ensure that your comments are clearly stated, please identify the specific question, or other section of this notice, that your comments address.

1.0 Background

In the fall of 2019, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) within the U.S. Department of Health and Human Services, funded MDRC and its partner, Child Trends, to conduct a project examining practices and programs aimed at reconnecting youth to school and work. This RFI is intended to help identify programs for the first major task of the project, which is to conduct a scan of programs and practices, including innovative approaches, aimed at improving education and employment outcomes for disconnected young people from low-income families and communities. The information gathered through this RFI will result in a public compendium that profiles selected programs operating in this area, particularly innovative programs. To ensure this project reaches the full range of programs operating in the United States, including new and innovative programs, we are seeking recommendations on programs to be screened for inclusion in the compendium. Specifically, we are seeking information about programs that provide services to help youth ages 16 to 24 advance on education and employment pathways.

2.0 Request for Information

Through this RFI, HHS seeks to gather feedback from public stakeholders—state and local government agencies, local program operators, and the people that we serve—to identify programs that aim to improve education and employment outcomes for the population of young people who are out of work and out of school, particularly those from low income families or communities, sometimes called disconnected or opportunity youth. Please note that we will consider all recommended programs, but not all submissions will be included in the compendium.

We are looking for programs that fit the following criteria:

- Serves young people ages 16–24 (may also serve adults).
- Targets young people who are out of school, out of work, or have other risk factors (low income family, or community; parenting; justice involved; foster care; experiencing homelessness; has a disability).

- Provides services in support of education or employment goals.
- Currently operating in the United States.

3.0 Key Questions

Please use the questions below to tell us about programs that you think we should consider for this project.

- 3.1 What is the program's full name?
- 3.2 What is the program's website?
- 3.3 Where does the program operate (city, state, region, or national)?
- 3.4 Please provide a brief description of the mission and main activities of the program.
- 3.5 Please indicate yes/no/not sure if the program serves young people with any of the following characteristics:
Yes/No/Not sure
 - 3.5a Ages 16 to 24
 - 3.5b Did not complete high school
 - 3.5c Not currently attending college/postsecondary education
 - 3.5d Low income family/community
 - 3.5e English Language Learners
 - 3.5f Homeless
 - 3.5g In foster care or aged out of foster care
 - 3.5h Pregnant/Parenting
 - 3.5i Involved in the juvenile or criminal justice system
 - 3.5j Has a disability

Dated: July 23, 2020.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation (HSP).

[FR Doc. 2020–16422 Filed 7–28–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space availability. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting 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: National Deafness and Other Communication Disorders Advisory Council.

Date: September 10–11, 2020.

Closed: September 10, 2020, 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NSC, 6001 Executive Blvd., Rockville, MD 20852 (Virtual Meeting).

Open: September 10, 2020, 1:30 p.m. to 4:00 p.m.

Agenda: Staff reports on divisional, programmatic, and special activities.

Place: National Institutes of Health, NSC, 6001 Executive Blvd., Rockville, MD 20852 (Virtual Meeting).

Closed: September 11, 2020, 10:00 a.m. to 10:40 a.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, NSC, 6001 Executive Blvd., Rockville, MD 20852 (Virtual Meeting).

Open: September 11, 2020, 10:40 a.m. to 2:00 p.m.

Agenda: Staff reports on divisional, programmatic, and special activities.

Place: National Institutes of Health, NSC, 6001 Executive Blvd., Rockville, MD 20852 (Virtual Meeting).

Contact Person: Craig A. Jordan, Ph.D., Director, Division of Extramural Activities, NIDCD, NIH, Room 8345, MSC 9670, 6001 Executive Blvd., Bethesda, MD 20892–9670, (301) 496–8693, jordanc@nidcd.nih.gov.

Information is also available on the Institute's/Center's home page: <https://www.nidcd.nih.gov/about/advisory-council>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: July 23, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

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