Opportunity Title: FDA Pediatric Drug Development Programs for Drug-Device Combination Products Fellowship
Opportunity Reference Code: FDA-CDER-2026-0005

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CDER-2026-0005

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- One educational or professional recommendation

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CDER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 4/30/2026 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

FDA Office and Location: A research opportunity is available in the Office of Translational Sciences (OTS) Office of Clinical Pharmacology (OCP) at the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA) located in Silver Spring, MD.

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

Research Project: Pediatric drug-device combination products pose a unique challenge to pediatric drug development especially for the younger children. Some of the challenges in using pediatric drug-device combination products include the delivery of inadequate doses for achieving therapeutic benefit and the age-appropriateness of delivery devices. While regulatory guidelines require sponsors to consider age-appropriate formulations, there are currently no requirements for the development of age-appropriate delivery devices. In this project, pediatric drug development programs for drug-device combination products will be systematically reviewed to gain a better understanding of the pediatric drug development of these products.

The selected fellow will be involved in the following activities related to the research project: collecting data from public and proprietary sources, analyzing research data, and contributing to presentation/publication of research findings. In addition to the project, the fellow will participate a

variety of educational activities, such weekly journal club meetings and project meetings, to better understand pediatric drug development and clinical pharmacology concepts. The fellow will be able to observe, but not participate in, the regulatory review process.

Learning Objectives: Under the guidance of the mentor(s), you will be involved in the following activities: (1) perform a literature search related to the background of the project, (2) create a database with the list of all drug-device combination products intended for use in pediatric population and collect data from the prescribing information and clinical pharmacology reviews related to the development program for these drug-device combination products, (3) analyze the data in collaboration with the mentor(s) (4) present scientific findings at project meetings, poster presentation, and write up a manuscript.

Mentor: The mentors for this opportunity are Gelareh Abulwerdi (Gelareh.Abulwerdi@fda.hhs.gov) and Elimika Fletcher (Elimika.Fletcher@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentors.

Anticipated Appointment Start Date: March 2026. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full-time.

Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

Citizenship Requirements: This opportunity is available to U.S. citizens and Lawful Permanent Residents (LPR) only.

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA Ethics Requirements

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If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications The qualified candidate should have received a bachelor's, master's, or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Life Health and Medical Sciences** (51 👁)

Affirmation I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)

and

I have read the FDA Ethics Requirements.