Opportunity Title: FDA Public Health and Regulatory Research Fellowship
Opportunity Reference Code: FDA-OPHSA-2023-0002

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

Reference Code FDA-OPHSA-2023-0002

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 maximum one-page cover letter highlighting candidate's interests in the fellowship and relevant experiences
- Two writing samples – technical, research, and/or policy oriented
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- Two educational or professional recommendations

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

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

Application Deadline 9/30/2023 11:59:00 PM Eastern Time Zone

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

Location: A research opportunity is available at the U.S. Food and Drug Administration (FDA), Office of Public Health, Strategy, and Analysis (PHSA). This opportunity is located on FDA's main campus in Silver Spring, MD, but options for fully remote (from U.S. locations) or partial in-person at FDA's main campus in Silver Spring, MD are available.

Research Project: PHSA conducts evidence-to-policy work via quantitative and qualitative research on emerging and priority public health issues such as health equity, drug availability and competition, and transparency. Under the guidance of a mentor, the fellow will assist on research projects to provide evidence to inform FDA's public health policy priorities. The fellow will be assigned to quantitative and qualitative research projects related to FDA's domestic and/or global regulatory research in the generic drug space. In addition to the mentor, the fellow will collaborate with subject matter experts across the FDA to accomplish project goals.

Potential projects include (but are not limited to) research and analysis of:

- Generic drug approvals and market competition.
- Assessment of falsified and substandard medical products in international settings.
- The quality of drug marketing applications submitted to the FDA.

Anticipated Start Date: **On or after June 1st, 2023.** All start dates are flexible.

Deadlines: The tentative deadline for applications is September 30th, 2023. However, the applications for this fellowship will be reviewed on a rolling-basis, and selections may be made at any time during the review process and before the application closing deadline. Thus, early submission is strongly encouraged.

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Participant Stipend: A competitive stipend, based on FDA criteria for candidate's education level (~$74,000 per year), is provided. In addition to the stipend, a supplement for health insurance is provided. The fellow will be eligible to obtain insurance coverage through the ORISE health insurance plan, or may obtain coverage under another insurance plan from another carrier

FDA Clearance: Any fellowship offer is contingent on successful completion of FDA's required security clearance (fingerprints and background check) and satisfactory assessment for conflicts of interest. The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three of the past five years for FDA to be able to complete a background check.

Questions: Please submit any inquiries to OPHSAFellows@fda.hhs.gov.

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 initial appointment is for one year (full-time), but may be renewed upon recommendation of FDA contingent on the availability of funds.** 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

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 must have received or is currently pursuing (expected within a year) a doctorate-level epidemiology, economics, or public health related degree from an accredited institution: Such as PhD, MD, PharmD, or other similar disciplines.. Degree must have

been received within five years of the appointment start date.

While at the FDA, the fellow will have additional learning opportunities such as attending workshops, professional conferences, high-level policy meetings with the director, staff, and FDA senior leadership as well as the opportunity to learn from other PHSA research, and to explore other parts of FDA.

Preferred skills:

- Experience in quantitative research (data collection, secondary data analysis, mathematical modeling, etc.) is highly desired
- Demonstrated ability to work independently

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (5 👁)
  - **Life Health and Medical Sciences** (19 👁)
  - **Mathematics and Statistics** (4 👁)
  - **Social and Behavioral Sciences** (6 👁)

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.