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Opportunity Title: FDA Public Health and Regulatory Research Fellowship
Opportunity Reference Code: FDA-OC-2024-0001

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

Reference Code FDA-OC-2024-0001

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
- A one-page cover letter
- 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.OC.other@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 6/1/2024 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis, and this opportunity will remain open until filled.**

A research opportunity is currently available with the U.S. Food and Drug Administration (FDA), Office of Public Health, Strategy, and Analysis (PHSA), under the Office of the Commissioner (OC), located in Silver Spring, Maryland.

Under the guidance of a mentor, the fellow will be trained 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 be trained closely by subject matter experts across the FDA to accomplish project goals. Potential projects include (but are not limited to) research and analysis of:

- 1) Generic drug approvals and market competition
- 2) FDA's foreign inspections of generic drug manufacturers
- 3) The quality of drug marketing applications submitted to the FDA

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.

Anticipated Appointment Start Date: June 1, 2024.

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, 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.

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Proof of health insurance is required for participation in this program. **The appointment is full-time at FDA in the Silver Spring, Maryland, area.** 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 should have received or be currently pursuing a master's degree in one of the relevant fields. Degree must have been received within the past five years, or be currently pursuing.

Preferred skills:

Experience in quantitative research (data collection, secondary data analysis, mathematical modeling, etc.) is highly desired; as well as a demonstrated ability to research independently.

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Master's Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (1 👁)
  - **Social and Behavioral Sciences** (1 👁)

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.)

I have read the FDA Ethics Requirements.