Opportunity Title: FDA Research Opportunity in the Landscape Assessment of 505G(a)(4) Drugs
Opportunity Reference Code: FDA-CDER-2023-1342

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

Reference Code FDA-CDER-2023-1342

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 11/30/2023 3:00:00 PM Eastern Time Zone

Description A research opportunity is available in the Office of Compliance (OC), Office of Unapproved Drugs and Labeling Compliance (OUDLC), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland. The project is to conduct a landscape assessment of drugs marketed as over-the-counter (OTC) deemed to be not generally recognized as safe and effective (GRASE) under the recently passed Coronavirus Aid, Relief, and Economic Security Act (CARES Act). This will be a proactive approach centered around consumer safety and protection.

Under the guidance of the mentor, the participant will gain experience in the current compliance regulatory framework of OTC monograph drug products, will learn about FDA's perspective to assess public health safety and efficacy associated to these products and learn from current existing expertise and novel search initiatives using different databases and online/social media analysis.

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. 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

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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 a Master's or Doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Familiarity analyzing large datasets and using databases.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17)
  - **Life Health and Medical Sciences** (48)

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.