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Opportunity Title: FDA Over the Counter (OTC) Drug Monograph Regulatory Analysis Fellowship
Opportunity Reference Code: FDA-CDER-2023-1304

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

Reference Code FDA-CDER-2023-1304

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 8/18/2023 3:00:00 PM Eastern Time Zone

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

A research opportunity is available in the Office of New Drugs/Office of Nonprescription Drugs, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

In 1972, The FDA initiated an Over the Counter (OTC) drug monograph review process to evaluate the safety and effectiveness of thousands of marketed OTC products. An OTC drug monograph serves as a kind of "rule book" for regulated industry in formulating OTC products by specifying "conditions of use" under which a given category of products are considered to be Generally Recognized as Safe and Effective (GRASE) and not misbranded. This review process is ongoing to modify and update the monographs to keep pace with changing science. The literature search results and related analyses of publicly available information will be used by the Office of New Drugs / Office of Nonprescription Drugs as background data for monograph reviews in support of FDA actions related to the OTC Drug Monographs.

Under the guidance of a mentor, the participant will train on conducting comprehensive literature searches on specific monograph drug active ingredients or other monograph condition; summarizing and analyzing relevant data from the literature searches; and summarizing and analyzing key findings, limitations, and data gaps from white papers and published data submitted to the public docket.

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.

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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 be currently pursuing or have received a doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Life Health and Medical Sciences** (4 👁)

Affirmation Have you 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.