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Opportunity Title: FDA Chemical Safety Testing Fellowship
Opportunity Reference Code: FDA-CFSAN-2023-0013A

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

Reference Code FDA-CFSAN-2023-0013A

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 cover letter including career goals (upload in the writing sample section)
- One 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.CBER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 12/29/2023 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available at the U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Additive Safety (OFAS), Division of Science and Technology located in College Park, Maryland.

FDA's Office of Food Additive Safety has developed a screening tool (called Expanded Decision Tree (EDT)) that screens and prioritizes chemicals for safety testing according to their toxic potential using a sequence of 47 structure-based yes or no questions, to which the answer either refers the user to another question or assigns the substance to one of six structural classes of toxic potential. Each EDT Class has a Threshold of Toxicological Concern (TTC) level associated with it. If a chemical's intake is not more than its class TTC level, the chemical is anticipated to have negligible risk at that intake level. The EDT is based on the Cramer et al. (1978) Decision Tree (CDT), current scientific information, and a newly created EDT Database (EDT DB) that contains up to date chemical, toxicological, and metabolism data for over 1,900 compounds.

Under the guidance of a mentor, the selected participant will be involved in the following research activities:

- Learn how to perform the quality control of the toxicological, metabolism and chemical information in the EDT DB
- Learn how to collect and evaluate additional toxicological data
- Learn how to collect additional metabolism data or predict metabolism for compounds with no metabolism information

The learning objectives of this appointment include:

- To learn how to maintain and perform the quality control of scientific databases
- To learn how to interpret and evaluate toxicological testing data and information, as well as learning about species differences in toxicity and learn about the relevance of animal

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toxicological data to humans
- To learn about metabolism in animals and humans and metabolic differences amongst various species, as well as learning to interpret and evaluate data and information from metabolism studies

Anticipated Appointment Start Date: September 1, 2023

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 12 months**, 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 College Park, 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 a bachelor's, master's or doctoral degree in one of the relevant fields, or be currently pursuing a master's or doctoral degree. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Good understanding of organic chemistry and biochemistry
- Completed coursework in toxicology, metabolism, anatomy, physiology, and/or clinical chemistry

Eligibility

- **Citizenship:** U.S. Citizen Only

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Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Overall GPA:** 3.00
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (3 👁)
  - **Life Health and Medical Sciences** (8 👁)

Affirmation

I have received a bachelor's, master's or doctoral degree within the past 5 years, OR am currently pursuing a master's or doctoral degree.

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.