**Opportunity Title:** FDA Secondary Pharmacology Analysis Fellowship
**Opportunity Reference Code:** FDA-CDER-2020-0571

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

**Reference Code** FDA-CDER-2020-0571

**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** 3/31/2021 9:36:26 AM Eastern Time Zone

**Description**

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

A research opportunity is available in the Office of Translational Sciences/ Office of Clinical Pharmacology (OCP), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

Secondary pharmacology data is regularly submitted with Investigational New Drug (IND) applications. These data are binding assays at multiple (80-100) targets that can assess a drug candidate's potential to induce adverse events. However, this data is currently housed with individual applications in the Electronic Document Room and is submitted in a PDF form, making it difficult to extract and analyze. This project will explore a data extraction and analysis tool to allow for better accessibility of these datasets.

The participant will be trained within multiple interdisciplinary teams across the Agency to learn about the regulatory submission and review process, which will provide a broad learning experience about the workings of the FDA and general public health. Additionally, the participant will gain understanding about the submission challenges surrounding secondary pharmacology data as well as the impact of secondary pharmacology and its relationship to adverse events.

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

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

Knowledge in data analysis is preferred.

## Eligibility Requirements

- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)