**Opportunity Title:** FDA Generic Drugs Research Fellowship
**Opportunity Reference Code:** FDA-CDER-2020-0514

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

**Reference Code** FDA-CDER-2020-0514

**How to Apply**

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. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

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** 9/30/2020 3:00:00 PM Eastern Time Zone

**Description**

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

Four research opportunities are available in the Office of Generic Drugs/Office of Research and Standards, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project in The Office of Generic Drugs/Office of Research and Standards will address scientific questions and issues that arise during generic drug application review. The goal of this project is to develop and improve methods for comparing products to facilitate the development and review of generic drugs; insight into new methods and technologies that may be used for drug development and application review. This may translate into eventual revision and drafting of new guidance, establishment of new research projects and input into regulatory submission reviews.

Under the guidance of a mentor, the participant will be trained on conducting searches of regulatory submissions to find information regarding drug product formulation, bioequivalence data, and communications to industry to understand a product's approval/review history and in vitro/in vivo drug performance. The participant will also conduct research on novel methods, technologies, databases/tools for improved characterization of a drug product, improved understanding of a drug product's performance, or improved databases/tracking tools for research. This training will prepare the participant for a successful career transition into regulatory science research - training that cannot be obtained elsewhere.

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 three 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

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

## Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Communications and Graphics Design** (1 👁)
  - **Computer, Information, and Data Sciences** (16 👁)
  - **Engineering** (1 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (10 👁)
  - **Physics** (16 👁)
  - **Science & Engineering-related** (1 👁)
  - **Social and Behavioral Sciences** (1 👁)