Opportunity Title: Pharmaceutical Environmental Assessment Research Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2017-0030

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

Reference Code FDA-CDER-2017-0030

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
- Two educational or professional references

All documents must be in English or include an official English translation.

If you have questions, send an email to FDArpp@orau.org. Please include the reference code for this opportunity in your email.

Description A research opportunity is available at the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), on the Environmental Assessment (EA) Team.

The EA Team implements the National Environmental Policy Act of 1969 (NEPA), which requires all federal agencies to assess the environmental impact of their actions. At FDA, the approval of a new drug application (NDA) is one such action. Applicants submit EAs with many of these applications, depending on the amount of active ingredient used and/or other factors. The EA Team uses the EAs to determine whether the action may significantly affect environmental quality. Recently finalized EA "Q&A" guidance informs drug applicants that additional ecological toxicity testing may be required for drugs with hormonal activity. Antimicrobial, additivity/synergism, and other properties also have been implicated for possible adverse environmental effects at low levels. In addition, human effects through environmental pathways have prompted public and internal inquiries for some drugs.

The EA Team is seeking an individual to help us better understand assessment techniques and possible mitigations for reducing risks from drugs in the environment, which in turn will help CDER to update current guidance for investigating and characterizing the ecological and public health relevance of drugs in the environment.

Participants may be involved in: identifying and characterizing the key ecological toxicity endpoints, study designs, and testing approaches to best assess risks of drugs with hormonal activity and other endpoints in the environment; reviewing and assessing literature regarding mitigation technologies and strategies for reducing risks from drugs in the environment; and drafting options for modifying CDER's approach for EA research and guidance and regulatory development.

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

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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 Silver Spring, MD area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications

Applicants must have received a doctoral degree in aquatic ecology, biology, biochemistry, toxicology, or a closely related field within five years of the desired starting date. Applicants close to completing or have completed their Masters degrees will also be considered.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Life Health and Medical Sciences** (6 👁)
  - **Other Non-Science & Engineering** (1 👁)
  - **Social and Behavioral Sciences** (2 👁)