Opportunity Title: Pharmacy Compounding Regulatory Analysis Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2016-0079

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

Reference Code FDA-CDER-2016-0079

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 in the Office of New Drugs at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

In 2013, FDA began implementing the drug compounding provisions of the Drug Quality and Security Act. Drug compounding by pharmacists or physicians is a long standing tradition in which health care professionals use bulk chemical substances to create oral, topical or other medications that are not otherwise commercially available as drug products. These compounded drug products are intended to meet the needs of individual patients who are perceived to derive unacceptable health outcomes from FDA approved drugs. The new FDA program evaluates the the safety and effectiveness of many bulk chemicals to treat various medical conditions, based on a public nomination process. This evaluation process will determine which bulk substances are appropriate for continued drug compounding.

The participant will be responsible for researching specific chemical substances and medical conditions that will be subject to FDA rulemaking. Responsibilities include providing summary data and analysis of available scientific literature published or submitted to the public docket and other activities per below:
-Conduct comprehensive literature search on specific chemical substances and the scientific information available regarding their use as drugs.
-Summarize and analyze relevant data from the literature search
-Summarize and analyze key findings, limitations, and published data submitted to the FDA.

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The literature search results and related analyses of publicly available information performed by the ORISE participant will be used by FDA regulatory scientists as background data for public advisory committee meetings and in support of FDA rulemaking related to pharmacy compounding.

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

Qualifications

A doctoral degree in biology, pharmacology, toxicology, public health received within five years of the desired starting date. Strong experience in review of published scientific literature; ability to analyze and summarize findings from the literature, and excellent writing skills preferred. Experience with clinical trials is optimal.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Academic Level(s):** Postdoctoral.
- **Discipline(s):**
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)