Opportunity Title: Nonprescription Drug Labeling Fellowship- FDA CDER
Opportunity Reference Code: FDA-CDER-2018-0331

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

Reference Code FDA-CDER-2018-0331

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 An opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), in Silver Spring, Maryland.

In 1999, the FDA published a final regulation (21CFR 201.66) establishing standardized content and format for the labeling of Over the Counter (OTC) drug products, Drug Facts Labeling (DFL). The DFL for OTC drug products is intended to make it easier for consumers to read and understand OTC drug product labeling and use OTC drug products safely and effectively. It has been over 19 years since the Drug Facts Labeling Rule was published. During this time, the prescription final rules have published, including the Physician's Labeling Final Rule (PLR) and the Pregnancy and Lactation labeling (Drugs) Final Rule. This project intends to explore whether changes need to be made to the 1999 final rule on the labeling content and format to further improve consumer understanding of the DFL.

Under the guidance of a mentor the participant may be involved in: reviewing the literature related to consumer understanding of the DFL to identify potential areas for improvement; assisting in development of questions and topics for discussion in a public workshop on the DFL and determining how many OTC DFLs have limitations in conveying important information about drug-drug interactions. The fellow will develop a working knowledge of OTC Drug Facts Labeling requirements, understand basic study design issues for label comprehension studies and learn how literature-based data may be applied to drug policy 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 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

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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.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.

Qualifications

A masters, or doctoral degree in social and behavioral sciences or other related field; must either be currently pursuing or have received the degree within the last 5 years of the start date of the appointment.

Eligibility Requirements

- **Degree:** Any degree received within the last 60 month(s).
- **Discipline(s):**
  - **Communications and Graphics Design** (1 👁)
  - **Other Non-Science & Engineering** (1 👁)
  - **Social and Behavioral Sciences** (3 👁)