

Opportunity Title: President's Emergency Plan for AIDS Relief - CDER Opportunity Reference Code: FDA-CDER-2017-0028

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

Reference Code FDA-CDER-2017-0028

How to Apply A complete application consists of:

- An application
- Transcripts <u>Click here for detailed information about acceptable</u> 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 <u>FDArpp@orau.org</u>. 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), in the Office of Communications/Division of Drug Information.

The Center for Drug Evaluation and Research (CDER) works to ensure drug products are safe, effective, and available to improve the health of Americans. CDER's Division of Drug Information (DDI) is currently responsible for drafting Public Assessment Reports (PARs) as part of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR is the U.S. Government initiative to help save the lives of those suffering from HIV/AIDS around the world, and PARs are used by patients and healthcare professionals where PEPFAR eligible products are used and have a direct impact on patients.

The office is seeking an individual to research the consistency of FDA package inserts from one generic to another as well as the reference listed drug for each product.

Participants may be involved in: drafting PARs, engaging with other staff on the process of PARs, learning about the FDA drug regulatory process, and participating in presentations as needed.

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 6 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.



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desired starting date. Proficiency in Microsoft Word (Mail Merge), interested in HIV AIDS, and strong scientific writing skills are preferred. Experience with scientific writing for consumers and an understanding of drug labeling is preferred

Eligibility Requirements

Eligibility • Degree: Bachelor's Degree received within the last 60 month(s).

## Requirements • Discipline(s):

- Communications and Graphics Design (2.)
- Life Health and Medical Sciences (45 )