

**Opportunity Title:** Regulatory Analysis Systems Management of ANDAs approved prior to 2009 Fellowship - FDA CDER

**Opportunity Reference Code:** FDA-CDER-2018-0121

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

**Reference Code** FDA-CDER-2018-0121

**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](mailto:FDArpp@orau.org). Please include the reference code for this opportunity in your email.

**Description** A postgraduate research opportunity is currently available in the Office of Generic Drugs/Office of Generic Drug Policy at the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA).

This project will conduct regulatory and historical research and analysis to identify the reference listed drug (RLD) for thousands of abbreviated new drug applications (ANDAs) in the generic drug review platform. The project's research will be documented and tracked, and information provided in a systematic manner. The project will enlarge our knowledge and understanding of the RLD for ANDAs.

Under the guidance of a mentor the participant may be involved in: researching historical and regulatory information for ANDAs to identify the RLD for ANDAs; documenting RLD information and research; systematically populating the generic drug review platform with the documented RLD information where necessary.

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, MD 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 complete a background check.*



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**Qualifications** Applicants must have received a Bachelor's degree within five years of the desired starting date, or completion of all requirements for the degree should be expected prior to the start date.

- Eligibility**
- **Degree:** Bachelor's Degree received within the last 60 month(s).
- Requirements**
- **Discipline(s):**
    - **Environmental and Marine Sciences** ([1](#) )
    - **Life Health and Medical Sciences** ([45](#) )

**Affirmation** Have you lived in the U.S. for three of the past five years?