Opportunity Title: FDA Bioequivalence of Complex Generic Products Fellowship
Opportunity Reference Code: FDA-CDER-2026-0012

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

Reference Code FDA-CDER-2026-0012

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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
- One educational or professional recommendation

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

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

Application Deadline 3/30/2027 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

FDA Office and Location: Multiple research opportunities are available in the Office of Generic Drugs/Office of Research and Standards (ORS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

Research Project: This research project is related to complex drug substances and complex formulations in the areas of parenteral, intrauterine, intravaginal, ophthalmic, otic, inhalation, nasal, topical, transdermal and transmucosal products to understand the formulations that have been approved under abbreviated new drug applications (ANDAs) and NDAs. The project will identify and develop in vitro, in vivo, or in silico techniques that may be capable of determining how various complexity factors can impact the performance of test products to their respective reference listed drug. It will also identify potential scientific gaps in the application of novel technologies for characterizing complex generic products to support bioequivalence and product development.

Learning Objectives: Under the guidance of the mentor, the participant will gain a comprehensive understanding of the scientific and regulatory challenges that must be considered when establishing bioequivalence for complex generic topical, transdermal and transmucosal drug products. This

will include combination drug-device products with device components that may themselves have degrees of complexity in design. In addition, the participant will gain knowledge in collaborating with cross-disciplinary teams to develop novel in vitro, in vivo, and/or in silico study designs for establishing bioequivalence with these products.

Mentor: The mentor for this opportunity is Yan Wang (Yan.Wang3@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: March/April 2026. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full-time.

Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

Opportunity Title: FDA Bioequivalence of Complex Generic Products Fellowship
Opportunity Reference Code: FDA-CDER-2026-0012

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications The qualified candidate should be currently pursuing or have received a doctoral degree in one of the relevant fields (e.g. pharmaceutical science, pharmacology, pharmacy, or a related area).

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (2 👁)
  - **Engineering** (4 👁)
  - **Life Health and Medical Sciences** (51 👁)

Affirmation I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)

AND

I have read the FDA Ethics Requirements.