Opportunity Title: FDA Fellowship - Consistent Approach to Maximum Daily Dose Determination
Opportunity Reference Code: FDA-CDER-2026-0109

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

Reference Code FDA-CDER-2026-0109

How to Apply ***To submit your application, scroll to the bottom of this opportunity and click 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
- 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.

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!

Application Deadline 7/17/2026 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 Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA) located in White Oak, 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. These efforts cover more than just medicines.

Research Project: Multiple Offices and Divisions determine, and rely on, the Maximum Daily Dose (MDD) for generic products, which has resulted in multiple MDD determinations for the same drug products. Inconsistent MDDs can make it difficult to set appropriate impurity thresholds, estimate maximum daily exposure (MDE) to impurities or excipients in context of safety evaluation, and to respond to requests for MDD determinations in Controlled Correspondences. The project entails identifying MDDs determined in the past 5 years and assess alignment with determinations made by other CDER offices and in current databases. A consistent approach will then be established, communicated throughout CDER and documented/wharehoused in a DCR MDD database.

Learning Objectives: Under the guidance of a mentor, you will have the opportunity to:

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- Learn the regulatory importance of Maximum Daily Dose (MDD) determinations for generic drug products and their role in safety evaluations.
- Learn how inconsistent MDD determinations can impact impurity threshold setting, maximum daily exposure (MDE) calculations, and responses to Controlled Correspondence requests.
- Learn to systematically collect and analyze MDD determinations made within the past five years across multiple offices and divisions.
- Learn to assess alignment and discrepancies between historical MDD determinations, other CDER office decisions, and existing regulatory databases.
- Learn to create and propose a consistent, science-based approach for determining and documenting MDD values.
- Learn to design and implement a centralized database (DCR MDD database) to warehouse and standardize MDD information.

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

Anticipated Appointment Start Date: 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 only.

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

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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.

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 have received a master's or doctoral degree in one of the related fields. Degree must have been received within the past five years.

Preferred skills:

- Strong background in pharmacology with clinical experience is preferred.

Point of Contact

Ashley

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Life Health and Medical Sciences** (51 👁)

Affirmation

I am a U.S. citizen.
I have read the FDA Ethics Requirements.