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Opportunity Title: FDA Fellowship - AI to Evaluate Maximum Daily Dose for Topical Drugs
Opportunity Reference Code: FDA-CDER-2026-0007

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

Reference Code FDA-CDER-2026-0007

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 4/30/2026 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available in the Office of Immunology and Inflammation (OII), Office of New Drugs (OND), 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: Maximum daily dose (MDD) refers to the highest amount of active ingredient dosed in a day according to drug product labeling. However, labeling of topical drug products often do not provide the precise quantity for administration. Thus, determination of MDD for topical drug products is labor intensive and may involve judgment over application procedure and body surface area estimation. To overcome such challenges, this project attempts to approach with AI model(s) in the evaluation of MDD of topical drug products. You will initially familiarize with FDA's IT system and take relevant courses and trainings related to clinical trials. Later, you will learn FDA's Elsa, a large language model-powered AI tool for use in extracting and summarizing information from application files and labeling and develop new generative and agentic AI models for testing in the evaluation of topical drug product MDD. The model(s) can be further improved and aligned with other FDA models upon input from CDER collaborators.

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Learning Objectives: You will have opportunities to (a) gain proficiency in relevant FDA software and systems on regulatory applications, their supportive clinical trials, review of their data, and approved labeling to provide a firm basis for a professional career in academic setting to conduct clinical trials; and (b) development of AI models for application to regulatory decision making, which is additionally valuable for opening up your future career opportunities.

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

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

Appointment Length: The appointment will initially be for nine months, 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

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.

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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 or be currently pursuing doctoral degree in one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (6 👁)
  - **Life Health and Medical Sciences** (51 👁)

Affirmation Have you 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.