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Opportunity Title: FDA Fellowship in Topical Drug Product Dosage
Opportunity Reference Code: FDA-CDER-2023-1359

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

Reference Code FDA-CDER-2023-1359

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 1/31/2024 3:00:00 PM Eastern Time Zone

Description This project is in the Office of Immunology and Inflammation (OII), Office of New Drugs (OND). Currently we need to define maximum daily doses (MDDs) for drug products based on approved labeling for the active drug ingredient(s). However, topical drug product administration is by application to body surface area(s) with units given for the drug product instead of the active ingredient(s). There is variability in dosing because each patient has unique body surface area for product application at a particular time which can change over the treatment course; it is also difficult to assure a standard thickness of the product applied to the skin. Despite these challenges, this project will attempt to establish the MDDs for topical drug products, as well as to provide training for an ORISE fellow for this research.

Under the guidance of the mentor, the fellow will (1) initially attain proficiency in the uses of DARRTS, gain skills in retrieving information from labeling via resources such as FDALabel, DailyMed, and Drugs@FDA and obtain expertise in CDISC data standards to review and analyze clinical data; (2) learn the use of Prescription Drug Labeling and distinguish labels with/without clear-cut information on dosing limits; (3) enhance critical thinking through exploration for relationship between MDD and administration variables and improvement in the determination of MDD for topical drug products; and (4) sharpen presentation skills and writing skills. The project will provide an environment and opportunities for experiencing how regulatory approaches are based on scientific principles and how to communicate these effectively.

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 one year, 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, Maryland, area. Participants do not become employees of FDA, DOE or the program

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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.

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 (biological sciences, computer science or medical informatics would be preferred). A doctoral degree in pharmacy with experience in informatics would be equally acceptable. Knowledge in data interpretation and use of software in the data, including familiarity with graphic representation is preferred. If having doctoral degree, the degree must have been received within five years of the appointment start date.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Computer, Information, and Data Sciences** (3 👁)
  - **Life Health and Medical Sciences** (3 👁)
  - **Mathematics and Statistics** (11 👁)

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.