

Opportunity Title: FDA Over the Counter (OTC) Drug Product Regulatory
Analysis of Microbial Risks: Case Study on Ophthalmic Eye Drops
Opportunity Reference Code: FDA-CDER-2026-0031

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

Reference Code FDA-CDER-2026-0031

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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 5/31/2026 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 at the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Office of New Drugs (OND) located 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 effort covers more than just medicines.

Research Project: This project examines microbial contamination risks associated with over-the-counter (OTC) drug products, with emphasis on sterility of ophthalmic eye drops with different packaging systems such as multi-dose preservative-free (MDPF) bottles, single-dose units (SDUs), and advanced delivery technologies. The research will analyze published literature, post-marketing data, and simulated-use studies to evaluate contamination pathways, packaging integrity, consumer misuse patterns, and labeling practices. You will be integrating current knowledge of microbiology, labeling, packaging technology, and consumer behavior to gain insights into potential microbial contamination risks. This project strengthens FDA's ability to protect public health by supporting evidence-based approaches to ensure safety through improved labeling and/or packaging recommendations that reduces consumer misuse and prevents infections. If a need to change the labeling is uncovered as a result of this research project, FDA has new and expedited procedures under OTC

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monograph reform to initiate an administrative order to make safety label changes to mitigate risks of serious adverse events associated with use of OTC monograph drug products. This research project is aligned with two critical FDA Focus Areas of Regulatory Research, specifically Product Safety Surveillance (e.g., to evaluate contamination rates across different OTC eye drop container closures systems), and Technologies to Reduce Pathogen Contamination (e.g., OTC eye drop antimicrobial technology in preservative free container closures systems).

Under the guidance of the mentor(s), you will 1) Conduct systematic literature reviews on microbial contamination in OTC drug products starting with a case study on ophthalmic eye drops; 2) Compare packaging types used in marketed OTC drug products; 3) Evaluate labeling statements and directions for use related to sterility maintenance; 4) Summarize microbiological findings (e.g., common contaminants, testing methods, risk factors); 5) Collaborate with FDA mentors within the Division of Nonprescription Drugs II, Office of Nonprescription Drugs to integrate findings into regulatory science discussions.

Learning Objectives: You will receive multidisciplinary training in:

- Regulatory science methods: Understanding how microbial risk assessment informs OTC drug monographs and labeling.
- Scientific writing and data synthesis: Developing a peer-reviewed manuscript for a regulatory science journal with data tables and visual infographics.
- Interdisciplinary collaboration: Engaging with microbiologists, chemists, biologists and labeling reviewers within the division to interpret data.
- Participate in internal scientific seminars, regulatory training courses, and FDA scientific poster sessions to strengthen their communication ability.

Mentor: The mentor for this opportunity is Sergio Coelho (sergio.coelho@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, in-person at the FDA White Oak Campus in Silver Spring Maryland.

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.

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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](#).

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. Degree must have been received within five years of the appointment start date.

Point of Contact [Ashley](#)

Eligibility • **Citizenship:** U.S. Citizen Only

Requirements • **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 6/30/2026 12:00:00 AM.

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- **Discipline(s):**

- **Chemistry and Materials Sciences** ([1](#) 👁)
- **Life Health and Medical Sciences** ([5](#) 👁)

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.