Opportunity Title: FDA Over the Counter (OTC) Drug Product Regulatory Analysis of Antigingivitis/Antiplaque Monograph
Opportunity Reference Code: FDA-CDER-2026-0032

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

Reference Code FDA-CDER-2026-0032

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 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 ORISE research project will analyze published literature to consider the oral microbiome and its role in the development of dental and periodontal diseases. The project's goal is to provide scientific updates for testing methodology employed to assess the effectiveness of antigingivitis/antiplaque drug products. Current FDA guidance for antigingivitis/antiplaque drug products relies on test methods that do not reflect contemporary understanding of oral microbiology. Existing regulatory final formulation test methods need to be reconsidered in light of two scientific advancements in the last two decades. First, the expansion of our understanding of oral microbiome composition and its microbial diversity across patient populations, including pediatrics, largely due to the revolutionary acceleration of DNA sequencing technology, driven by the development of Next-Generation Sequencing (NGS) and its subsequent advancements. Second, the increased understanding that oral microorganisms predominantly exist as complex polymicrobial biofilm

communities while our existing methods for effectiveness testing primarily focus on planktonic bacterial growth.

You will help conduct a comprehensive literature analysis of oral microbiome dynamics and biofilm-mediated pathogenesis in the gingivitis disease state and evaluate the alignment of the current state of basic and applied science with existing antiplaque/antigingivitis monograph regulatory test methods.

Under the guidance of the mentor(s), you will help 1) Conduct a systematic review of peer-reviewed literature from 2003-present using databases including PubMed, Embase, and Web of Science, focusing on keywords related to oral biofilms, gingivitis pathogenesis, antiplaque testing, and oral microbiome characterization across a broad patient population; 2) Review existing FDA monographs, guidance documents, and regulatory precedents for antigingivitis/antiplaque product testing requirements.

Learning Objectives: Educational and Training Components: You will receive multidisciplinary training in:

- Regulatory science methods: Understanding how final formulation test methods informs OTC drug monographs and labeling.
- Scientific writing and data analysis/synthesis: Developing a peer-reviewed manuscript for a regulatory science journal with data tables and visual infographics.
- 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.

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 Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 6/30/2026 12:00:00 AM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Life Health and Medical Sciences** (5 👁)

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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.