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Opportunity Title: FDA Research Opportunity on Molecular Biological Reagents for Characterization of Live Biotherapeutic Products
Opportunity Reference Code: FDA-OWH-2026-0005

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

Reference Code FDA-OWH-2026-0005

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.OC.other@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 3/27/2026 4:55:24 PM Eastern Time Zone

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

FDA Office and Location: A fellowship opportunity is available immediately with the U.S. Federal Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) located in Silver Spring, Maryland. Funding for this opportunity will be provided by the Office of Commissioner (OC), Office of Women's Health (OWH).

Research Project: Live Biotherapeutic Products are preparations of live bacteria that are being investigated for the treatment or prevention of specific human diseases. They include products commonly referred to as probiotics. For use in clinical trials, particularly in more vulnerable subjects, demonstrating the absence of contaminating organisms, especially pathogens, is a major safety-indicating parameter. This can be problematic due to the large number of product organisms, which may obscure typical culture methods. We are attempting to develop specific reagents to eliminate the product organisms to allow detection of contaminants by simple, yet sensitive, culture methods. Among the approaches we are investigating are lysin proteins - derived from bacteriophage, and bacteriocins - proteins that bacteria produce to kill other bacteria. In addition, we are developing reagents to specifically label bacteria. These will be used in assays that, in a mixture of therapeutic bacteria, will identify each bacterial species in order to demonstrate potency (number of each viable strain) and stability (potency over time). Modalities being investigated for this aspect of the project include binding domains of lysin proteins, camelid antibodies raised against whole bacteria, and other antibodies against surface structures.

Learning Objectives: If selected, you will have the opportunity to learn and become proficient at laboratory techniques including microbiological techniques, DNA cloning, western blot analysis, protein purification, fluorescence microscopy, and flow-cytometry.

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Mentor: The mentor for this opportunity is Scott Stibitz (Earle.Stibitz@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.

Stipend: Participants will receive a stipend commensurate with education and experience. A stipend supplement to defray costs of health insurance can be added if the fellow is responsible for paying for their own health insurance.

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

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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 bachelor's or master's degree in one of the relevant fields (Biological Sciences), or be currently pursuing the degree. The degree must have been received within 5 years of the appointment start date.

Preferred skills/ knowledge:

- Basic microbiological techniques - preparation of growth media and propagation of bacterial strains
- Basic DNA cloning techniques - preparation of plasmid DNA, PCR, restriction and ligation, and transformation
- Basic electrophoresis techniques - agarose gels for DNA and acrylamide gels for proteins
- Lab experience
- An interest in Microbiology

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (48 👁)

Affirmation

I am a U.S. citizen, or 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.