

Opportunity Title: FDA Fellowship at CFSAN: Infant Formula Notification Packaging Review **Opportunity Reference Code:** FDA-CFSAN-2024-0023

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

Reference Code FDA-CFSAN-2024-0023

How to Apply *Connect with ORISE...on the GO!* Download the new ORISE GO mobile app in the <u>Apple App Store</u> or <u>Google Play Store</u> to help you stay engaged, connected, and informed during your ORISE experience and beyond!

A complete application consists of:

- An application
- For this opportunity, an unofficial transcript or copy of the student academic records, such as a high school diploma, printed by the applicant or by academic advisors from internal institution systems may be submitted. 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 <u>ORISE.FDA.HFP@orau.org</u>. Please include the reference code for this opportunity in your email.

Application Deadline 8/31/2024 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: Several research opportunities are available within the Food and Drug Administration (FDA) in The Center for Food Safety and Applied Nutrition (CFSAN), Office of Regulatory Science (ORS) located in College Park, Maryland. **Remote options are available.**

The Center for Food Safety and Applied Nutrition, known as CFSAN, provides services to consumers, domestic and foreign industry and other outside groups regarding field programs; agency administrative tasks; scientific analysis and support; and policy, planning and handling of critical issues related to food, dietary supplements, and cosmetics.

Research Project: This opportunity will be to conduct the review of packaging materials used in contact with infant formula. The ORISE fellow will evaluate data submitted on identity, composition, and regulatory information to confirm that all materials used in infant formula packaging are authorized for their specific intended uses. The ORISE fellow will learn about the regulatory processes and laws for food contact substances, food additives, and infant formula, and in turn use that knowledge to conduct these reviews. The ORISE fellow will present his/her/their review to the infant formula packaging lead and identify any remaining questions or clarifications that need to be addressed, as well as provide support to other infant formula packaging reviewers. This support may take the form of searches in the historical record for previous IFNs and other relevant evaluations of food contact substances, or other technical aid pertaining to

OAK RIDGE INSTITUTE FOR SCIENCE AND EDUCATION

💹 ORISE GO



The ORISE GO mobile app helps you stay engaged, connected and informed during your ORISE experience – from application, to offer, through your appointment and even as an ORISE alum!





Opportunity Title: FDA Fellowship at CFSAN: Infant Formula Notification Packaging Review **Opportunity Reference Code:** FDA-CFSAN-2024-0023

the supporting databases.

Learning Objectives: The ORISE fellow will learn:

- The regulatory processes and laws for food contact substances, food additives, and infant formula
- How to conduct a packaging review for an infant formula submission
- Engage in intra and interoffice communications regarding ongoing infant formula submissions
- Conduct research regarding previous reviews of food contact substances
- Use knowledge of chemical identity to determine whether a food contact substance is authorized for its intended use
- Manage inventories and databases pertaining to these reviews

Anticipated Start Date: September 1, 2024.

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.

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 <u>FDA Ethics for Nonemployee Scientists</u>.

FDA requires ORISE participants to read and sign their FDA Education and



Opportunity Title: FDA Fellowship at CFSAN: Infant Formula Notification Packaging Review **Opportunity Reference Code:** FDA-CFSAN-2024-0023

> 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 master's or doctoral degree in the one of the relevant fields (e.g. biology, chemistry, food sciences, etc). Degree must have been received within the past five years, or currently pursuing.

Preferred skills:

· Knowledge of FDA food additive regulations to assist with the above listed duties.

Point of Contact Ashley Letson

- Eligibility Citizenship: U.S. Citizen Only

- **Requirements** Degree: Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
 - Minimum Overall GPA: 3.00
 - Discipline(s):
 - Chemistry and Materials Sciences (12. (12)

 - Life Health and Medical Sciences (7. (2))
 - Physics $(2 \odot)$
 - 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.)

I have read the FDA Ethics Requirements.