

Title 21 Vacancy Announcement

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Human and Animal Food Operations (OHAFO)
Office of Human and Animal Food Operations East (HAF-E)
Infant Formula Cadre Supervisor

Application Period: March 29, 2023 – April 17, 2023

<u>Area of Consideration:</u> Open to current FDA employees only. United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Infant Formula Cadre Supervisor Series: AD-0696

Location(s): ORA Headquarters, and all FDA Offices and Resident Posts in the following FDA Districts - Atlanta, Baltimore, Chicago, Cincinnati, Dallas, Denver, Detroit, Florida, Kansas City, Los Angeles, Minneapolis, New England, New Jersey, New Orleans, New York, Philadelphia, San Francisco, San Juan, Seattle

Work Schedule: Full Time

Full Performance Band Level: Band D

Salary: Starting at \$132,368

Title 21 Band(s): D, Pay Table 1

Travel Requirements: Up to 25% travel

Bargaining Unit: This is a non-bargaining unit position

<u>Incentives:</u> Incentives may be authorized; however, this is contingent upon availability of funds. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 4 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives may include recruitment or relocation incentives in accordance with FDA, Title 21 Policy.

This position is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of this authority.

Additional information on 21st Century Cures Act can be found here:

Version: 11/2021

21st Century Cures Act Information

Introduction

The Food and Drug Administration is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe, and that all such products marketed in the United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured, packaged and regulated. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

The Office of Regulatory Affairs (ORA) is at the forefront of building a public health safety net for today's complex, global regulatory environment. ORA professionals work in a range of program areas and locations, with 227 offices and 13 laboratories throughout the United States. As the lead office for all FDA field activities, ORA serves as the agency's direct connection with regulated industry through a) inspections of firms and plants producing FDA-regulated products, b) investigations of consumer complaints, emergencies and criminal activity, c) enforcement of FDA regulations, d) sample collection and analysis, and e) review of imported products.

To view our ORA Vision, Mission, and Values please visit: https://www.fda.gov/about-fda/office-regulatory-affairs/ora-vision-mission-and-values.

The Office of Human and Animal Food Operations (HAF) oversees the coordination, interpretation and evaluation of the FDA's overall field inspections and compliance efforts in the areas of human and animal food and other products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). Additionally, the HAF program focuses on national and international inspection of a variety of diverse and complex food products and production processes including infant formula, medical foods, low acid canned food and thermal processing, etc.

The HAF Program oversees field operations that encompass both food safety and food defense activities to determine compliance with the Food Safety and Modernization Act (FSMA) as well as other FDA laws and regulations, and to ensure the safety of consumers. In addition, the HAF program routinely coordinates emergency response activities, rapid identification of suspect tainted foods, trace forward, and tracebacks to swiftly address emerging issues which have potential to compromise public health.

The Infant Formula Cadre Supervisor, who reports directly to the Deputy Program Director,

HAF-E, is expected to have knowledge of inspections of regulated products and manufacturers; provides expert advice and counsel to the HAF Program Leadership and other Agency leaders on inspectional and compliance operations and emergency response activities related to Infant Formula and Medical Food activities in the field.

Duties/Responsibilities

- Responsible for ensuring completed assignments align with the focus of investigational and related operations. Additionally, the incumbent is responsible for technical and quality review of work products.
- Coordinates work activities to ensure timely completion of emergency investigational operations to rapidly detect, trace, and remove potentially harmful food products in the public domain.
- Works collaboratively with division leadership as needed to provide training, coordinate completion of high-risk food facility inspections and support emergency response efforts.
- Coordinates work activities to ensure the annual foreign and domestic workplan for infant formula and medical foods facilities is accomplished.
- Fully participates in all phases of Program planning and policy formulation, sharing the Program Director's responsibility for the development of substantive programs and plans which will permit optimum accomplishment of program responsibilities within assigned resources.
- Routinely communicates orally or in writing on specialized or complex information to FDA Senior Leaders.
- Determines the Staff's overall policies and approaches to be followed to achieve the mission of the Agency consistent with ORA established policies and procedures.
- Develops specific projects and activities from broad program goals through the application of sound managerial and leadership concepts and practices, with a view toward enhancing the national impact of the Agency's activities.
- Maintains continuous crucial review of all policy and project objectives to ensure overall
 program plans are carried out as efficiently and effectively as possible with maximum
 utilization of resources.
- Establishes and maintains cooperative professional relationships with personnel throughout
 the Agency, other federal, state, local and international agencies, and representatives of
 major organizations representing interests regulated by FDA to share relevant information
 on compliance policies and procedures, monitors program activities; confer with other
 subject matter experts; obtains clarification.

This position requires the incumbent have a current Driver's License.

Supervisory Responsibilities:

The Infant Formula Cadre Supervisor is responsible for directing a professional group of

investigators performing inspections and investigations of regulated industry, focusing primarily on Infant Formula and Medical Food Manufacturers. The supervisor is responsible for defining jobs; planning, assigning, reviewing, and evaluating the work and performance of those employees.

The supervisor reviews, approves and disapproves leave requests; defines technical work requirements and milestones; evaluates the organization and employee accomplishments by accepting or rejecting work products; and presents and defends organization and employees work to senior management and other offices.

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959 must be registered with the Selective Service.
- One year supervisory probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. All employees must pass a
 security investigation. Failing to pass the background check may be grounds for removal
 or legal action. If hired, you may be subject to additional investigations at a later time.
- This position requires the incumbent have the following: current Driver's License.
- This position requires up to 25% travel.

Qualifications

To be placed into a Title 21 position, candidates must meet the following criteria:

- 1. Scientific, Technical, and Professional Fields
- 2. Qualified and Outstanding Candidates
 - a. Qualified applies to all candidates for Title 21 appointments. The FDA OTS will use the basic requirements defined in the <u>OPM Qualification Standards</u> as a baseline for comparing experience levels and other candidate attributes for relevant positions.

b. **Outstanding** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 position, the candidate(s) must meet the following <u>required</u> qualifications. *Please note: Additional education and experience listed that is not indicated as* <u>required</u> is preferable and desired. Candidates who do not meet the "desired" criteria will <u>not</u> be excluded from consideration for this position.

Education Requirement: The education must have been obtained at a college, university, or an accrediting body recognized by the Secretary, <u>U.S. Department of Education</u> at the time the degree was obtained. For more information please see: <u>OPM Occupational Series Qualification Requirements.</u>

Consumer Safety Series 0696

Professional Experience:

- Advanced knowledge of Human and Animal Food inspections and investigations (with experience in Preventive Controls for Human Food and Infant Formula Compliance Programs)Experience collaborating with top level officials within an organization as well as officials from federal, state or city governments, professional health organizations, the regulated industry, consumer organizations, etc. to accomplish goals.
- An advanced degree (or equivalent experience) in law, science, public health, management, or other related field from an accredited college/university.
- Comprehensive knowledge of and skill in selecting, adapting, and applying investigative methods and negotiating techniques.
- Broad knowledge of a variety of various scientific and technical disciplines are necessary to carry out tasks related to the regulation of the food industry.
- Skill in planning and coordinating the work of others.
- Demonstrated knowledge of written and verbal communication practices and principles to prepare and present reports, findings, and recommendations.

Education Transcripts

<u>SUBMITTING YOUR TRANSCRIPTS:</u> Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

<u>FOREIGN EDUCATION:</u> If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. For more information about this requirement, please visit the <u>U.S. Department of</u>

Education website for Foreign Education Evaluation.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Background Investigation/Security Clearance Requirements: If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Ethics Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information please visit the FDA Ethics web page: https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity

Equal Employment Opportunity Policy

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor. Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation

Reasonable Accommodation Policy

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis. A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits. Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when: An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job. An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis. Learn more about disability employment and

reasonable accommodations or how to contact an agency.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

How to Apply

Applicants must submit a letter of interest addressing experience in the major duties and responsibilities of the position, a detailed current résumé, redacted SF-50 (for federal employees only), and transcripts (with foreign credentials evaluation if applicable) to the ORA Executive Recruitment Team at: oraexecutiveandscientificrecruitment@fda.hhs.gov. Applications will be accepted through April 17, 2023. Applicant resumes may be shared with hiring official within the OHAFO with a similar job vacancy. Applicants can opt out of this process by annotating resume with "do not share". Please reference Job ID: Infant Formula Cadre Supervisor in the subject line.

Announcement Contact

For questions regarding this Title 21 position, please contact oraexecutiveandscientificrecruitment@fda.hhs.gov.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

FDA is an equal opportunity employer.

