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)
Consumer Safety Officer - Investigator (Critical Foods)

Application Period: May 3, 2023 – May 31, 2023

Area of Consideration: 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: Consumer Safety Officer – Investigator (Critical Foods)

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

Salary: Starting at $112,015

Work Schedule: Full Time

Full Performance Band Level: C

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

Travel Requirements: Up to 50% travel

Bargaining Unit: This is a bargaining unit position

Incentives: Incentives may be authorized; however, this is contingent upon funds availability. 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 of the United States Code (21 US Code 379d-3a) as amended by the 21st Century Cures Act of 2016, section 3072 and the Consolidated Appropriations Act of 2023, Section 3624. 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 the 21st Century Cures Act can be found here:
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 mission of the Office of Regulatory Affairs (ORA) is to protect consumers and enhance public health by maximizing compliance of FDA regulated products and minimizing risk associated with those 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.

This position is a Cross Cutting position and supports the development, review and regulation of food, specifically Critical Foods including the Infant Formula and Medical Food commodities. The CSO will primarily perform inspections and investigation of Infant Formula, Medical Food facilities and related industries both domestically and foreign.

This position reports to the Critical Foods Cadre Supervisor, HAF-E.

Duties/Responsibilities

- The Critical Foods Cadre Investigator demonstrates and is recognized for a high level of competence in a range of inspection types with expertise in conducting Infant Formula and Medical Food inspections and investigations. Plans, conducts, and directs highly technical, complex, and multi-faceted inspections and in-depth investigations related to the production, control, and testing of food products, and is highly skilled in interview and investigation techniques. Routinely evaluates and makes recommendations on the state of compliance of a firm/individual involved in infant formula, medical foods, or other FDA regulated product manufacturing.
- Assignments covers complex domestic and foreign investigations and inspections of various industry establishments. The investigator independently conducts inspections, investigations, and sampling. The inspection or investigation may result in considerable attention and review in the media, the Department, Congress, or other forces inside or outside the Agency. Inspections cover all types of products and problems within the area of assigned responsibility.
- Investigates and evaluates the adequacy of novel or complex practices to determine compliance with the regulations where only limited guidance documents are available.
- Interacts with and advises various levels of officials representing the establishments subject to regulatory review. The incumbent initiates contact with industry officials to obtain information on regulatory and scientific documents and to discuss the status of investigations.
- Assists the immediate supervisor in planning inspections, investigations, sample collections, and related activities in assigned responsibility; training new personnel and higher graded personnel, as appropriate; interacts with foreign industry and foreign government personnel. Developmental assignments include assisting higher level employees in inspections or other field activities, meetings, and conference calls with regulated industry.
- Conducts re-inspections to follow up with non-compliant industry establishments.
- Independently performs investigations involving complaints of injury or death attributable to products regulated by the FDA.
- Performs analyses and evaluation of data and documented information gathered during inspections and investigations to ensure that documentation and practices are in compliance with Federal laws, rules, and regulations. Documents and organizes required evidence, data, and other information to support violations noted during inspections, investigations, and sample collections.
- Frequently serves as the lead investigator for team inspections or may serve as a team member. The employee gathers scientific and technical comments, assists with the preparation of reports relevant to the inspection, and contributes to status reports for inspections and investigations under review.
- Prepares final reports, position papers and other written documentation that support investigative findings and recommendations. Reports are developed, well-written and timely in accordance with quality elements.

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

Supervisory Responsibilities:
This is not a supervisory position.

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 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 up to 50% travel. This will often require the Investigator to be away from the duty station for up to two to three weeks at a time. International and domestic travel is required.

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 OPM Qualification Standards 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 **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not 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.S. Department of Education at the time the degree was obtained. For more information please see: OPM Occupational Series Qualification Requirements.

Consumer Safety Series 0696

Professional Experience:

- Experienced at the full performance level as an investigator in inspectional and investigative techniques in the human and animal food program area specifically infant formula and medical foods inspection types.
- Comprehensive knowledge of and skill in selecting, adapting, and applying investigative

methods and negotiating techniques.

- Must be a recognized field technical expert/authority in terms of developing new approaches, methods, policies, procedures, and evidence, when situations are encountered that may result in regulatory action.
- 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 to adapt precedents and existing strategies which allow occupational projects to meet unusual needs or demands and serves as a principal contributor for the assigned specialty areas on team-based projects.
- Ability to coordinate a team project by providing technical oversight and direction for a variety of principal team members representing related professional disciplines, and evaluates and presents plans, designs, reports, and correspondence concerning projects and product issues.
- Knowledge of and skill in selecting, adapting, and applying investigative methods and negotiating techniques to conduct complete and professional inspections and investigations, persuade reluctant persons and officials to provide information or access to information, and persuade industry representatives to agree to terms needed to achieve compliance.
- Skill in planning and carrying out assignments, resolving most conflicts that arise, coordinating the work with others as necessary, and interpreting policy on own initiative in terms of established objectives. In some assignments, the employee also determines the approach to be taken and the methodology to be used. The employee keeps the supervisor informed of progress and potentially controversial matters.
- Demonstrated knowledge of written and verbal communication practices and principles to prepare and present written reports, findings, and recommendations; develop analyses that are used for presentations.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: 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.

FOREIGN EDUCATION: 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.S. Department of 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 May 31, 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

Consumer Safety Officer - Investigator (Critical Foods) 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.