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 or West (HAF-E /HAF-W)
Investigator II

Application Period: December 1, 2023, to May 31, 2024

Area of Consideration: Open to all qualified United States Citizens. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Investigator II

Series: AD-0696

Location(s):
E4 – Jacksonville, FL; Miami Lakes, FL; Maitland, FL; Tallahassee, FL
E6 - South Bend, IN; Indianapolis, IN
W3 - Dallas, TX; Houston, TX
W4 - Lakewood, CO; Salt Lake City, UT; Tempe, AZ
W5 - Alameda, CA; San Jose, CA; Fresno, CA; Stockton, CA; Sacramento, CA; Irvine, CA; San Diego, CA; Ontario, CA; Long Beach, CA; Woodland Hills, CA

Salary: Starting at $82,764 (Band A)
Starting at $99,200 (Band B)

Work Schedule: Full Time

Title 21 Band(s): Band A/B

Full Performance Band Level: Band B

Travel Requirements: Up to 50%

Bargaining Unit: This is a bargaining unit position.

Hiring Incentives: 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:
21st Century Cures Act Information

Introduction

The Food and Drug Administration (FDA) 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 and abroad.

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 12 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.

The mission of the Office of Regulatory Affairs is to protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products. To view our ORA Vision, Mission, and Values please visit: https://www.fda.gov/about-fda/fda-organization/office-regulatory-affairs.

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.

Duties/Responsibilities

The Investigator II, Band A, demonstrates competence and conducts inspections of various industry establishments, such as manufacturers, re-packers and own label distributors in the human and animal food area resulting in a range of human and animal food inspection types and food-related investigations. These types of inspections and investigations will account for a level greater than 90% of the CSO's inspectional/investigative work.

Inspections and Investigations

- Serves as an investigator for the Office of Human and Animal Foods in the Office of Regulatory Affairs.
- The incumbent independently conducts inspections, investigations, and sampling at human and animal food facilities to ensure compliance with FDA laws, policies, and regulation of human and animal food commodities.
- Assists the immediate supervisor in planning inspections, investigations, sample collections, and related activities in the area of assigned responsibility; training new personnel, as appropriate; training foreign government personnel.
- Incumbent 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.
- Developmental assignments include assisting higher level employees in inspections or other field activities, meetings, and conference calls with regulated industry.
- Incumbent conducts re-inspections to follow up with non-compliant industry establishments on previously noted violations. In situations where compliance is not offered, it is enforced through other methods, including administrative action, informational agency meetings, and legal court actions.
- Performs other duties as assigned.

Analysis and Reporting

- The incumbent will perform analyses and evaluation on data samples and documented information gathered during inspections and investigations to ensure that documentation and practices follow federal laws, rules, and regulations.
- Documents and organizes required evidence, data, and other information to support violations noted during inspections, investigations, and sample collections.
- For team inspections, employee gathers scientific and technical comments from team members, assists with the preparation of reports relevant to the inspection, and contributes to status reports for inspections and investigations under review.
- May assist in training state and local government officials to ensure compliance with federal laws.
- May testify as an expert witness in administrative hearings and judicial proceedings.

- Prepares final reports, position papers and other written documentation that support investigative findings and recommendations. Reports are developed and well-written in accordance with quality elements.

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.
- Applicants selected for this position will be subject to reasonable suspicion and post-accident drug testing upon hiring. To demonstrate commitment to the HHS goal of a drug-free workplace and to set an example for other Federal employees, employees not in a testing designated position may volunteer for unannounced random testing by notifying their Drugfree Federal Workplace Program Point of Contact upon hiring.

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 Cures appointments. The FDA OTS will use the basic requirements defined in the Title 21 qualifications 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.
Education/Experience Requirement: Candidates must meet the following:

Education: The degree must be in quality assurance/management, data science, statistics, computer forensics, epidemiology, pharmacy, public health, engineering, food science, law or regulations, or related healthcare or science field. The degree must be from an accredited program or institution.

To qualify for Band A candidate must have:
- A bachelor's degree and (2) years of comparable experience; or
- A master's degree and (1) year of comparable experience; or
- A Ph.D. with no experience

To qualify for the Band B candidate must have:
- A bachelor's degree and (3) years of comparable experience; or
- A master's degree and (2) years of experience; or
- A Ph.D. and (1) year of experience

OR

Experience: To qualify for Band A without a bachelor's degree, candidate must have at least 4 years of comparable experience. To qualify for Band B without a bachelor's degree, candidate must have at least 5 years of comparable experience.

Comparable experience is defined as experience with FDA, a state or federal partner agency, or in an FDA-regulated industry or organization providing investigative or compliance services to an FDA-regulated industry, focused on evaluating or ensuring compliance with FDA or related public health laws and regulations.

Work environment: While some work is performed in an adequately lighted and climate-controlled office, onsite investigations, inspections, and sample collections may involve exposure to moderate risks or discomforts such as high levels of noise, extremes of heat, cold or humidity, dust, uneven surfaces and slippery floors, moving parts of machinery, irritant fumes, and extremely adverse conditions during natural and other disasters such as floods, fires, hurricanes, etc. Observance of safety precautions is required. The employee will be required to use protective clothing and equipment such as masks, gowns, coats, boots, goggles, gloves, or shields. The investigator may travel to work in areas with security concerns and will be required to work collaboratively with internal FDA and external partners to mitigate concerns.

Additional Requirements: The investigator must possess a valid U.S. driver's license to drive a

government or privately owned motor vehicle. Candidates for this position must complete a statement regarding their physical ability and may be required to undergo physical examination because the position requires: The need to work long and unscheduled hours; Exposure to all kinds and extremes of weather and noise; The need to lift heavy objectives up to 50 pounds, walk, bend, stand, stoop, kneel, and climb; The need to meet the vision, hearing, and olfactory requirements necessary to perform the work of this position; Travel approximately 50 percent of the time, which will often require the Investigator to be away from the duty station for up to two to three weeks at a time.

Desired Education and Professional Experience: Our ideal candidate will have a degree in biological sciences, microbiology, food science, chemistry, food technology, nutrition, food engineering, epidemiology, veterinary medical science, or related scientific fields that provided knowledge directly related to human and animal food investigator work.

Experience for Band A: Our ideal candidate will have:

Knowledge and skill in applying a wide range of complex professional theories, concepts, principles, standards, to determine, execute, and explain actions that modify standard practices, equipment, devices, processes, known techniques and resolve a wide variety of complications and constraints contained in traditional projects.

- Skill to adapt precedents and existing strategies which allow occupational projects to meet unusual needs or demands 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.
- Experience in evaluating and presenting 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,
- Ability to 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.
- Ability to apply judgment in interpreting and adapting guidelines, such as agency policies, regulations, precedents, and work directions for application to specific cases or problems. The employee analyzes results and recommends changes.
- Skill in making decisions to assess unusual circumstances, variations in approach, and incomplete or conflicting data.

Experience for Band B: In addition to the skills/experience listed for Band A, the ideal candidate for Band B will also have the following skills and experience:

- Skill in planning, conducting, and leading highly technical, complex, and multi-faceted inspections and in-depth investigations, and skill in interview and investigation techniques.
- Skill in analyzing and evaluating complex data samples and documented information gathered during inspections and investigations and utilizes novel approaches as needed to ensure compliance with federal laws, rules and regulations.
- Ability to prepare final Establishment Inspection Report (EIR), investigations memoranda and proposed or final endorsements for inspections and investigations.
- Ability to evaluate and make recommendations on the state of compliance of a firm/individual involved in human and animal food manufacturing, or other FDA regulated product manufacturing.

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 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 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

Applications will be accepted from all qualified U.S citizens. Applicants must submit the following: 1) a letter of interest (in pdf format) **including name of preferred city(ies)**, 2) a detailed current résumé, 3) college transcripts (with foreign credentials evaluation if applicable) 4) for current federal employees only, a current SF-50 with only year of birth and last four digits of social security number redacted.

IMPORTANT: The application must show this job reference ID and location code in the subject line: **8-Investigator II-HAF Location Code(s).** E.g., 8-Investigator II-HAF-E4,E6.
Send the above-mentioned documents to ORA Investigator Hiring at: ORAInvestigatorHiring@fda.hhs.gov.
NOTE: It is your responsibility to ensure the job ID and location is noted in the subject line and the required documentation is submitted prior to the closing date for your application to be considered.

Applications will be accepted through May 31, 2024.

Applicants may be selected in a location not listed on this announcement. Candidate resumes may be shared with hiring officials within ORA with similar job vacancies. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact

For questions regarding this Title 21 position, please contact ORAInvestigatorHiring@fda.hhs.gov and include the following job reference ID**: 8-Investigator II-HAF** in the subject line.

Interested in investigative work? Consider joining the FDA's Office of Human and Animal Foods

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

FDA is an equal opportunity employer.