



Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Import Operations (OIO)
Investigator II / Senior Investigator I

Application Period: April 15, 2024 – July 15, 2024, or until all positions are filled.

Area of Consideration: 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: Investigator II / Senior Investigator I

Series: AD-0696

Location(s): Multiple vacancies in the following locations: Nogales, AZ; San Diego, CA; Miami, FL; Miami Lakes, FL; Eastport, ID; Itasca, IL; Covington, LA; Winchester, MA; Baltimore, MD; Owings Mills, MD; Houlton, ME; Detroit, MI; Maplewood, MO; Sweetgrass, MT; Pembina, ND; Newark, NJ; Alexandria Bay, NY; Buffalo, NY; Champlain, NY; Jamaica, NY; Ogdensburg, NY; Brunswick, OH; Philadelphia, PA; Memphis, TN; San Juan, PR; Houston, TX; Laredo, TX; Pharr, TX; Falls Church, VA; Portsmouth, VA; Highgate Springs, VT; Blaine, WA; Seattle, WA

Salary: \$82,764 - \$109,506 (Band A)
\$99,200 - \$133,845 (Band B)

Work Schedule: Full Time

Title 21 Band(s): Band A, Band B, Table 1

Full Performance Band Level: Band B

Travel Requirements: Up to 25% travel.

Bargaining Unit: This is a bargaining unit position.

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.

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 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 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 Office of Import Operations (OIO) provides advice and counsel to the Associate Commissioner for Regulatory Affairs (ACRA) and other Agency senior leaders on import program operations and activities, and compliance matters. OIO coordinates Agency import activities with U.S. Customs and Border Protection (CBP), including the development and institution of joint regulations, procedures, policies, and operations. Coordinates activities with other Federal agencies and foreign governments through interagency agreements, memoranda of understanding, and informal working relationships.

Duties/Responsibilities

The Investigator II / Senior Investigator I has demonstrated and is recognized for a high level of competence in the full range of establishments regulated within the OIO program such as: inspections and investigation of domestic imports and foreign facilities; investigations supporting admissibility decisions for all FDA-regulated commodities imported into the U.S. including hands-on product reviews/sampling and assessment of compliance factors. These types of inspections and investigations will account for a level greater than 90% of the Investigator's inspectional/investigative work.

Assignments involve a combination of scientific and regulatory responsibilities which usually call for several atypical inspectional or intensive investigative approaches to be applied to a wide variety of regulatory functions or scientific evaluations; and include sample collections, product examinations, establishment inspections, unusual or novel special investigations and conducting objective surveys and emergency activities within the assigned area of responsibility. The Investigator II will also perform international inspections.

Inspections and Investigations:

- Independently plans and conducts regulatory inspections and in-depth investigations of various imported products to include sample collections, field examinations, label examinations, filer evaluations, and emergency activities.
- Independently plans and conducts regulatory establishment inspections of importers to ensure compliance with statutory and regulatory requirements such as Foreign Supplier Verification Programs inspections and Seafood HACCP Importer Verification inspections.
- Assignments are frequently complicated by a variety of diverse imported products, ingredients, and additives; highly specialized and sophisticated medical products; complex labeling; record documentation; or uncooperative management.
- Incumbent conducts inspections and investigations to follow up with non-compliant industry establishments on previously noted violations. In situations where compliance is not offered, it is enforced through the detention and refusal process, responding to emergency import situations, warning letters, increased screening, agency meetings and legal court actions.
- The Investigator II may perform import entry review requiring decisions to release or detain FDA regulated commodities based on document review, product examination and/or sampling following established guidance. The entry reviewer may also issue routine assignments to inspectors and investigators for field examination and sampling.
- Performs routine audits of entry filers (those firms submitting information when presenting FDA regulated products for entry into the U.S.) to assure proper data submission to FDA.
- Performs other duties as assigned.

Analysis and Reporting:

- Incumbent performs analyses and evaluation on import history and 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, sample collections, field and label examinations, or entry filer audits.

- Developmental assignments include assisting higher level employees in meetings and conference calls with importers, entry filers, consignees, and partner government agencies; assisting in team reviews by gathering scientific and technical comments from team members, assisting with the preparation of letters and correspondence relevant to the review; and contributing to status reports for submissions and investigations under review.
- 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 basic incomplete or missing information on regulatory and scientific documents and to discuss the status of investigations. Prepares final reports, affidavits, and other written documentation that support investigative findings and recommendations.
- Testifies as an expert witness in administrative hearings and judicial proceedings.

Supervisory Responsibilities: This is a nonsupervisory role.

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 later.

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

b. **Qualified** applies to all candidates for Title 21 appointments.

To qualify for this Title 21 Cures 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 Requirements: Candidate 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 comparable experience; or
- A Ph.D. **and** (1) year of comparable experience

OR

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

Additional Requirements of this Position:

- This position requires the incumbent to have the following current license and/or certification: Must possess a valid 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 objects 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.
- Position may include shift work and/or weekend work.
- Travel approximately 25 percent of the time which may require Investigator to be away from the duty station for up to two to three weeks at a time.

Desired Experience:

BAND A: Our ideal candidate will have:

- Knowledge and skill in applying critical thinking as it pertains to a wide range of complex professional theories, concepts, principles, standards, and methods to determine, execute, and explain actions that modify standard practices, equipment, devices, processes, and well-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 and serves as a principal contributor for the assigned specialty areas on team-based projects.
- 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.
- 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.

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:

- 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.
- Skill in making decisions to assess unusual circumstances, variations in approach, and incomplete or conflicting data.

- 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 the importation of FDA regulated products, or those who file entries on behalf of others.

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: 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

The United States Government does not discriminate in employment based on 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

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 accommodation when: An applicant with a disability needs accommodation to have an equal opportunity to apply for a job. An employee with a disability needs accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request 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.

Additional Information

Hiring 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 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: recruitment, relocation, student loan repayment (for government employees only), PCS and creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

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 Drug-free Federal Workplace Program Point of Contact upon hiring.

How to Apply

Applications will be accepted by all qualified applicants. United States Citizenship is required. Applicants must submit a letter of interest addressing experience in the major duties and responsibilities of the position, a detailed current resume, SF-50 (redacted for birth year and SSN – for federal employees only) and college transcript(s) showing degree was awarded (with foreign credentials evaluation if applicable). A diploma will not be accepted as part of your application. All required materials should be sent to: ORAInvestigatorHiring@fda.hhs.gov. Applications will be accepted through July 15, 2024, or until all positions have been filled.

IMPORTANT: Applicants must show this job reference ID in the email subject line: **8-Inv II-OIO-name of preferred location(s)**.

Announcement Contact

For questions regarding this Title 21 position, please contact ORAInvestigatorHiring@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.

