Associate Investigator & Investigator I
Investigator
Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Import Operations (OIO)
Division of Southwest/Southeast/Northeast/Northern Border/West Coast Imports

Summary:
The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA) Office of Import Operations (OIO) and being filled under FDA's Title 21 hiring authority. This hiring authority was passed by Congress in December 2016, to improve FDA's ability to recruit and retain scientific, technical, and professional experts in certain occupational series that "support the development, review, and regulation of medical products." The FY23 Omnibus Appropriations Bill expanded the hiring authority to include cross-cutting positions and individuals that support the development, review, and regulation of food and cosmetics in addition to medical products. Both statutes amended the FD&C Act 21 USC. This hiring authority is a streamlined hiring authority, outlined in 21 USC 379d-3a, as amended by the 21st Century Cures Act of 2016, § 3072 and the Consolidated Appropriations Act of 2023, § 3624.

Learn More About This Agency:

Become a part of the Department that touches the lives of every American.
At the Department of Health and Human Services (HHS) you can give back to your community, state, and country, by making a difference in the lives of Americans everywhere! HHS is the principal agency for protecting the health of citizens. Join HHS and help to make our world healthier, safer, and better for all Americans.

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 U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Office of Regulatory Affairs (ORA) 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.

Title 21 Pay Table 1, Band W/GS-7 equivalent & Band Y/GS-9 equivalent
Minimum – Band W: $55,924; Band Y: $68,405
Maximum – Band W: $74,155; Band Y: $90,704

Overview

Open & Closing Date: August 5, 2024 – November 5, 2024
Salary Range: $55,924 - $74,155 or $68,405 – $90,704
Band: AD-W (GS-7 equivalent) or AD-Y (GS-9 equivalent)
Occupational Series: 0696
Duty Location: Miami, FL; Miami Lakes, FL; Memphis, TN; Nashville, TN; Louisville, KY; Savannah, GS; Anchorage, AK; San Diego, CA; Maplewood, MO; Dallas, TX; Houston, TX; Laredo, TX; Falls Church, VA; Jamaica, NY; Houlton, ME; Champlain, NY; Ogdensburg, NY; Blaine, WA; Sweetgrass, MT; Pembina, ND; Detroit, MI; Itasca, IL; Buffalo, NY; El Segundo, CA; Honolulu, HI; Tacoma, WA; Seattle, WA; Carson, CA; Long Beach, CA; Cincinnati, OH; College Park, GA; Nogales, AZ; Brownsville, TX; Pharr, TX
Remote Job: No
Telework Eligible: Determined upon selection
Travel Required: Up to 50%
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: *DO NOT CHANGE
Promotion Potential: Yes, Band B
Supervisory Status: No
Security Clearance: No

Drug Test: No
Position Designation: Non-Sensitive / High Risk (Public Trust) / Tier 4 / SF 85P
Trust Determination Process: Suitability/Fitness

This job is open to: Open to the Public

Hiring Path Clarification Text: You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

Duties

As Associate Investigator (Band W) or Investigator I (Band Y), the incumbent has demonstrated and is recognized for a moderate level of competence in the full range of commodities regulated within the boundaries of an FDA Program such as foods, drugs, medical devices, imports, etc. Assignments involve a combination of scientific and regulatory responsibilities which usually call for a number of atypical inspections, or intensive investigative approaches to be applied to a wide variety of regulatory functions or scientific evaluations; and include the sample collections, establishment inspections, unusual or novel special investigations.

Inspections and Investigations:

- Receives advanced training, through classroom and on-the-job instruction, to provide a more thorough understanding of and exposure to FDA laws and regulations, administrative policies, import operations, and the various methods employed in the conduct of establishment inspections, sample collections, entry review, filer evaluation audits, special investigations, and emergency operations.
- Independently carries out the more common and ordinary import assignments in which the employee has received specific or related training. These assignments vary according to the program to which the employee is assigned but typically are restricted to application of well-defined guidelines to unsophisticated operations to assess the degree of consistency with regulatory practices and efficacy of quality controls.
- Collects samples, conducts field and label exams, and performs other import inspection and investigational activities, review for compliance with import regulations and laws, and records review, etc. Performs necessary tracing and tracking of products and establishes documented jurisdiction over products through established methods. The incumbent must be familiar with sampling schedule guides and billing and shipping procedures of transportation companies.
- Normally accompanies experienced investigators in the conduct of more complex inspections, investigations, field operations and filer evaluation audits. Such assignments involve import practices which require timely and effective interaction with importers, brokers, and carriers as well as other government agencies such as Customs and Border Protection. The primary purpose for such interaction is directed toward data

integrity and evaluation of quality controls employed by the regulated industries to prevent importation of violative FDA regulated products.
- Assists other experienced investigators in the investigation of unusual consumer complaints, e.g., contaminated products, foodborne outbreaks, etc. which are under FDA jurisdiction. Conducts other investigations where information can be obtained from known sources and is not likely to be deliberately concealed or falsified.
- Performs other duties as assigned.

Analysis and Reporting:
- Obtains, documents, and organizes all required evidence, data, and other information to support inspectional or investigational findings, sample collections, and filer evaluation audits.
- Prepares written reports showing results of the inspection/investigation and submits to the supervisor or higher graded investigator for review and evaluation.
- Accompanies experienced investigators to gain exposure in providing evidence to support professional testimony in court cases in support of legal action.

Supervisory Responsibilities: This is a non-supervisory role.

Requirements

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- 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. Please go to http://www.sss.gov for more information.
- One-year probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation Requirement: 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.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.

- 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 25-50 percent of the time, which may require the investigator to be away from the duty station for up to two to three weeks at a time.

Qualifications

Minimum Years of Experience is the new standard, rather than specialized experience, for determining and validating a Title 21 candidate's band. This standard applies across all Title 21 positions. (Please use this Link for reference).

In order to qualify for the **Associate Investigator** (Band W) or **Investigator I** (Band Y) positions which fall under the **0696 Series**, you must meet the following requirements by 11:59pm EST on **November 5, 2024.**

In order to qualify for an **Associate Investigator** (Band W) or **Investigator I** (Band Y), AD-0696, you must meet the following requirements:

Basic Qualification Requirements:

This Investigator job family covers professional positions that conduct inspections in FDA regulated industries and prepare and submit reports accompanied by supporting evidence documenting violations of the FD&C Act and other laws, regulations, and requirements administered by FDA. The position investigates and/or inspects FDA-regulated industry globally and evaluates compliance with U.S. laws and regulations in order to promote a culture of safety and quality with the objective of preventing unsafe, ineffective and/or defective products from becoming available to patients and consumers or used in clinical trials while facilitating appropriate development of novel products. FDA's enforcement of the laws and regulations protects patients and consumers from products that are impure, unsafe, ineffective, improperly, or deceptively labeled or packaged, or in some other way dangerous or defective. Investigators routinely examine products; collect samples; conduct inspections of establishments that design, make, process, hold, or distribute FDA-regulated products; and otherwise gather information and evidence to document objectionable conditions and assess compliance with U.S. law and regulations. Investigators apply critical thinking to evaluate manufacturing processes, design practices, facility and material controls, supply chains, quality management systems, laboratory analyses, and clinical investigation programs to assess

compliance with U.S. laws and regulations and to support advancements and innovations. Investigators continuously maintain required certification and credentials; provide internal and external stakeholder outreach, assistance, and education; and may mentor less experienced personnel. These positions require knowledge of various scientific fields such as biochemistry, biology, biotechnology, chemistry, data science, digital health, engineering, epidemiology, food engineering, food processing technologies, food safety, healthcare, medical technology, microbiology, nutrition, pharmaceutical science, pharmacology, public health, quality assurance, and quality management.

Education/Experience Requirement: Candidates must meet the following:

Education: A bachelor's degree or higher 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 W candidate must have:

- A bachelor's degree or higher with no experience

To qualify for the Band Y candidate must have:

- A bachelor's degree **and** (1) year of comparable experience; or
- A master's degree or higher with no experience

OR

Experience: To qualify for Band W without a bachelor's degree, the candidate must have at least 2 years of comparable experience. To qualify for Band Y without a bachelor's degree, the candidate must have at least 3 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.

Desired Experience:
Associate Investigator - Band W: Our ideal candidate will have:

- Knowledge and skill in applying critical thinking as it pertains to a range of professional theories, concepts, principles, and methods to determine, execute, and explain actions standard practices, equipment, devices, processes, and well-known techniques and resolve a wide variety of complications and constraints contained in traditional projects.

- Ability to use computer applications to accomplish projects, designs, plans, and reports; to perform and interpret analyses and computations for unknown factors; and to define relationships in factual matters involving well-understood issues.
- Skill in conducting and performing investigations using the scientific method including performance monitoring and quality assurance principles and conducting research by applying accepted and relevant business, and organizational practices.
- Ability to receive training in Food and Drug Program Division operations, including Food and Drug laws and regulations, their application and enforcement, import operation practices employed in the regulated industries, investigation and inspection methods and techniques designed to assess the degree of compliance with import and applicable domestic laws and regulations, good manufacturing practices, quality controls, laboratory operations, etc., enforcement policy and philosophy, the rules of evidence, and basic requirements for observing and recording, with emphasis on clear and concise report writing.

Investigator I - Band Y: In addition to the skills/experience listed for Band W, the ideal candidate for Band Y will also have the following skills and experience:

- Knowledge and skill in applying a professional, concepts, principles, and methodology sufficient to research, analyze, interpret, evaluate, and carry out difficult but conventional assignments; to determine relevancy and use of aesthetic, factual, economic, financial, and professional information; and to prepare and evaluate conventional plans, designs, specifications, and related documentation.
- Skill in conducting and performing analytical investigations using the scientific method including performance monitoring and quality assurance principles and conducting research by applying accepted and relevant business and organizational practices.
- Ability to recognize serious public health hazards where timeliness and departure from the usual procedures are essential.
- Demonstrated experience or ability to perform~~s~~ special investigations under detailed instructions, for example, tracing reports of contamination and collecting appropriate samples for laboratory examination.
- Experience accompanying experienced investigators to gain exposure and interaction with importers, brokers, carriers, and other government agencies such as Customs and Border Protection.

Education

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 employee, you are not exempt from transcript requirements.

TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. You must submit an official transcript, unofficial transcript, or a list including courses, grades earned, completion dates, and quarter and semester hours earned.

Transcripts must identify a degree type, date degree conferred, and identify the major if using education to meet basic degree requirements.

Education must be accredited by an accrediting institution recognized by the U.S. Department of Education in order for it to be credited towards qualifications. Therefore, provide only the attendance and/or degrees from schools accredited by accrediting institutions recognized by the U.S. Department of Education.

If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional requirements.

Electronic Transcript Caution: If you have obtained your transcripts electronically, the file might contain security measures that could prevent our application system from reading the file. Therefore, you should consider asking the institution to provide the file in a non-secure electronic format. Alternatively, you could scan or take a photo of the printed copy of the transcript. If your uploaded transcript cannot be read by our system, you may receive consideration and credit for the information we can access.

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 further information, visit the U.S. Department of Education website for Foreign Education Evaluation.***

To be acceptable, the foreign credential evaluation must include/describe at a minimum, the following information: (1) The type of education received by the applicant; (2) The level of education in relation to the U.S. education system, and state that its comparability recommendations follow the general guidelines of the International Evaluation Standards Council; (3) The content of the applicant's educational program earned abroad, and the standard obtained; (4) The status of the awarding foreign school's recognition and legitimacy in its home country's education system; and (5) Any other information of interest such as what the evaluation service did to obtain this information, the qualifications of the evaluator, and any indications as to other problems such as forgery.

Note: *Some positions require the completion of specific courses or a specified number of credit hours. Therefore, the foreign credential evaluation should provide information similar to that of an official transcript, to include a list of the courses taken, quarter and/or semester hours awarded, the cumulative grade point average (GPA), honors received, if any, date degree awarded.*

Applicants can request an evaluation from a member organization of one of the two national associations of credential evaluation services listed below:

1. National Association of Credential Evaluation Services (NACES)
2. Association of International Credentials Evaluators (AICE)

Credential evaluations are not free, and applicants are responsible for the cost of the selected service.

For more information about this requirement, please visit the U.S. Department of Education website for Foreign Education Evaluation.

Additional Conditions of Employment:

- **Pre-employment physical required:** No
- **Drug testing required:** No
- **License Required:** Yes
- **Mobility agreement required:** No
- **Immunization required:** No
- **Bargaining Unit:** National Treasury Employees Union (NTEU), 3591
- **Telework eligible position**: Determined upon selection and is at the discretion of the supervisor.
- **Remote eligible position**: No
- **Financial disclosure statement, OGE-450, required:** Please be advised that this position may be subject to FDA's prohibited financial interest regulation and may require the incumbent of this position to divest certain financial interests. Applicants are advised to seek additional information on this requirement from the hiring official before accepting this position.

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.

Additional Information:

- **Additional selections may be made for similar positions within the commuting area(s) of the locations listed through this vacancy announcement.**
- **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: moving expenses, recruitment, or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

- **If you are serving or have served in the last 5 years (from** 12/01/2023**) as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment.** You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. *See Political Appointee FAQ - OPM for more.*
- 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.

All requirements must be met by November 5, 2024; only education and experience gained by this date will be considered. You must continue to meet all requirements throughout the entire hiring process.

How you will be Evaluated:

You will be evaluated for this job based on how well you meet the qualifications above.

This is a Title 21 announcement. Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

If you are referred to the hiring manager for consideration, you may be further evaluated based on an interview; review of requested work samples, writing samples, most recent performance evaluation(s), or professional references; or results of an oral presentation or work-related test.

Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Please follow all instructions carefully. Errors or omissions may affect your eligibility.

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, 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 November 5, 2024, or until all positions have been filled.

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

NOTE: It is your responsibility to ensure the job reference ID is noted in the subject line and the appropriate required documentation is submitted prior to the closing date for your application to be considered.

Announcement Contact

For questions regarding this T21 position, please contact ORAInvestigatorHiring@fda.hhs.gov. and include the following job reference ID in the subject line: **8-Assoc. Inv/Inv I-OIO-Q**.