Deputy Office Director for Import Operations
Supervisory Investigator
Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Office of Inspections and Investigations (OII)
Office of Import Operations (OIO)

Summary:
The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Office of Inspections and Investigations (OII), 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 Inspections and Investigations is to protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products. To view our OII Vision, Mission, and Values, please visit: https://www.fda.gov/about-fda/fda-organization/office-inspections-and-investigations.

The Office of Inspections and Investigations (OII) is at the forefront of building a public health safety net for today's complex, global regulatory environment. OII professionals work in a range of program areas and locations, with offices throughout the United States. As the lead office for

all FDA field inspection, investigation, import and emergency response related activities, OII partners with internal and external agency stakeholders to identify, collect, and evaluate evidence that empowers integrated regulatory decision making. OII inspects regulated products and manufacturers, and reviews imported products offered for entry into the United States. In pursuit of its mission, OII also works with its state, local, tribal, territorial, and foreign counterparts.

The Office of Import Operations (OIO) provides advice and counsel to the Associate Commissioner for Inspections and Investigations (ACII) and other Agency senior leaders on import program operations and activities, and compliance matters. OIO coordinates Agency import activities with the U.S. Customs and Border Protection (CBP), including the development and institution of joint regulations, procedures, policies, and operations. OIO coordinates activities with other Federal agencies, state and local governments, and foreign governments through interagency agreements, memorandum of understanding, and informal working relationships. OIO is organized into headquarters and field divisions, comprising four headquarters divisions and five field divisions. The five field divisions: Division of Northern Border Imports (DNBI), Division of Northeast Imports (DNEI), Division of Southeast Imports (DSEI), Division of Southwest Imports (DSWI) and Division of West Coast Imports (DWCI).

Title 21 Pay Table 4, Band G/>GS-15 equivalent
Minimum – $213,491
Maximum – $307,312

Overview

Open & Closing Date: November 25th, 2024 – December 9th, 2024
Salary Range: $213,491 - $307,312
Band: AD-G (>GS-15 equivalent)
Occupational Series: 0696
Duty Location: Silver Spring, MD
Remote Job: No
Telework Eligible: No
Travel Required: Up to 25%
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band G
Supervisory Status: This is a supervisory role.
Security Clearance: Top-Secret/Sensitive Compartmented Information (TS/SCI)
Drug Test: Yes
Position Designation: Special Sensitive / High Risk / Tier 5 / SF86
Trust Determination Process: National Security

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

The Deputy Office Director for Import Operations (DDIO), in his/her capacity serves as the principal advisor to the Assistant Commissioner for Import Operations (ACIO) and the Associate Commissioner for Inspections and Investigations (ACII) for operational direction. In addition, the incumbent serves as the supervisor of the following Import Divisions: Southwest Imports, Southeast Imports, Northeast Imports, Northern Border Imports, and West Coast Imports.

Supervisory Responsibilities: The DDIO closely shares with the ACIO in providing executive leadership in the development, implementation and evaluation of regulations and policies as they relate to OII's broad national and import programs and activities to ensure the safety of FDA-regulated products. Additionally, the incumbent:

- Oversees the implementation of the enforcement policy of the Food Safety Modernization Act (FSMA) mandates, which safeguards the safety of imported FDA-regulated food and feed products. For example, the DDIO will have direct oversight of new FDA food safety innovations like the Foreign Supplier Verification Program (FSVP), and certification programs to ensure imported FDA-regulated food and feed products are produced in compliance with FDA laws and regulations.
- Enhances transparency initiatives for sharing compliance information and enforcement data to promote better risk-based product approaches both domestically and internationally.
- Provides leadership and direction on the application of risk management and program evaluation techniques to regulatory compliance activities so that limited resources can provide the most public health promotion/protection at the least cost to the public.
- Works closely with Agency risk management and program evaluation experts, including those in the Centers and the Commissioner's Office, to identify opportunities for enhanced coordination and better approaches to identifying, prioritizing, and managing risk through compliance programs and enhanced collaboration within FDA and counterpart governmental agencies, domestically and abroad, and other interested stakeholders.

Working in coordination with the ACIO, the DDIO:

- Negotiates the multi-year work plan covering both planned and unplanned work between the program manager and the Centers which is binding on both parties to carry out unless and until it is modified with the agreement of both parties.

- For planned work: Works with the Centers to identify the nature, quantity and geographic location of the work that needs to be done and can be planned. These would include such diverse and critical activities as surveillance inspections, for cause inspections, import review and sample collections, and laboratory testing and applied research needs.
- For unplanned work: Designs, develops and implements plans that provide estimates for emerging public health concerns such as: preapproval inspections, investigating complaints, and required investigations of incidents that suggest Federal Food, Drug, and Cosmetic Act (FD&C Act) violations and/or public health concerns.

Work Plan Execution Management:

- Represents OII in joint monitoring of the execution of the import work plan and, in consultation with the ACII, negotiates on behalf of OII any necessary adjustments required throughout the year.
- Monitors performance for adherence to plan; and takes corrective action to course correct as necessary.
- Negotiates modifications to plans and agreements for OII with the Centers as needed and ensures all impacted OII parties are informed of changes in a timely manner.

Workforce Development and Training:

- Ensures that training of specialized staff for the import program meets current and future needs through continuing education. Assures consistency of performance standards for import inspectors and compliance officers and a level of expertise consistent across the Centers.
- Designs and develops, in consultation with the ACIO, ACII, Principal Deputy ACII and other OII leadership on long range strategic, scientific, and tactical plans for the specialization of OII resources including investigational staff and compliance staff to meet the Office/Centers current and future needs. Then manages, working with OII's OTED, in the implementation of those needs in OII including recruitment and training/retraining needs.
- Serves as the import program focal point and expert for the long-term change process of moving OII to a program/product alignment of resources to assure that FDA speaks with one voice on import regulatory programs, all the while assuring that year-by-year existing structures implement the public health risk-based priorities of the import program. Under the incumbent's guidance and oversight the will eventually be transformed into specialized units within OII operating in program-based staffs and will be directed and managed by commodity-specific offices and in the case of imports be led by this incumbent.

Budget Formulation and Execution of Import Resources:

- Participates in the formulation of the OII import budget request in concert with the

Centers and OII'S Office Management (OM) to assure OII's total import needs are represented and justified. Monitors the formulation process and supports OII on all import matters pertaining to the budget formulation process advising OII officials when they are negotiating at the FDA, DHHS, OM and Budget (OMB) and Congressional levels regarding export action planning items.

- Works with OM and other OII leadership monitors the budget execution of the import program resources to assure conformance with Congressional and OMB allocations.
- Represents and speaks for the ACIO and ACII in discussions, meetings, conferences, and consultations with top-level departmental and agency officials, national/international industry representatives, academic organizations and groups, foreign officials, members of Congress and/or their representatives, personnel from other executive departments and independent Federal agencies, State and local governmental counterparts and others to secure and provide information concerning critical and significant issues, actions and regulatory activities related to OII programs and to resolve complex regulatory questions and issues that arise

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 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 later. This position requires the incumbent to have access to highly classified data, documents, facilities and/or materials related to national security, thus demanding a high degree of public trust, and requiring the incumbent to possess and maintain a Top-Secret Security clearance.
- In addition, the position requires eligibility for access to Sensitive Compartmented Information (SCI), other intelligence-related Special Sensitive information, or involvement in Top Secret Special Access Programs) (SAP)

- All applicants tentatively selected for this position will be required to submit to urinalysis to screen for illegal drug use prior to appointment and be subject to random, reasonable suspicion, and post-accident drug testing upon hiring. Appointment to the position will be contingent upon a negative applicant drug test result.
- 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.

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 **Deputy Office Director** (Band G) position which fall under the **0696 Series**, you must meet the following requirements by 11:59pm EST on **December 9th, 2024.**

In order to qualify for the **Deputy Office Director** (Band G), AD-0696 position, 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 the Band G candidate must have:

- A bachelor's degree and eight (8) years of comparable experience; or
- A master's degree and seven (7) years of comparable experience; or
- A doctoral degree and five (5) years of comparable experience.

OR

Experience: To qualify for Band G without a bachelor's degree, the candidate must have at least fifteen (15) 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 Education and Professional Experience:

- An advanced degree in law, science, public health, management, or other related field from an accredited college/university.
- Experience formulating and establishing strategies and influencing strategy and policy relating to compliance, enforcement, or import activities.
- Executive level experience (i.e., GS-15 or above or equivalent, 2nd or 3rd line supervisory experience) in directing a large organization of 50 or more employees.
- Experience directing subordinate managers.
- Experience establishing organizational policy, including the implementation of new legislative authorities or other significant mandates.
- Demonstrated ability to communicate effectively both internally and externally to a large number of staff located in different geographic areas.
- Experience collaborating with top level officials within the organization as well as officials from Federal, state, or city governments, professional health organizations, the regulated industry, consumer organizations, etc. to accomplish goals.

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.

See the Application Manager Documentation for tips on submitting your paper-based documents.

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:** Yes
- **License Required:** Yes, a valid U.S. Driver's license.
- **Mobility agreement required:** No.
- **Immunization required:** No.
- **Bargaining Unit:** This is a non-bargaining unit position.
- **Telework eligible position**: No.
- **Remote eligible position:** No.
- **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.

- **Financial disclosure statement, OGE-278, 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:

- **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.*

All requirements must be met by the closing date of this announcement: December 9th. 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 candidates. United States Citizenship is required. Please submit a letter of interest addressing your experience in the major duties and responsibilities of the position, a detailed current resume, and college transcript(s) (with foreign credentials, if applicable) showing degree was awarded (a diploma will not be accepted as part of your application) to: OIIExecutiveandScientificHiring@fda.hhs.gov.

Applications will be accepted through **December 9th, 2024.**

Applicants must reference the job ID: **4-OIO-DDIO-G** in the email subject line.

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

Announcement Contact

For questions regarding this Title 21 position, please contact OIIExecutiveandScientificHiring@fda.hhs.gov and include the following job reference ID in the subject line: **4-OIO-DDIO-G-Q**