TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Enforcement and Import Operations (OEIO)

Position: Assistant Commissioner for Import Operations (ACIO)

Series: 0301, 0696

Location(s): Dallas, TX., Detroit, MI., Long Beach, CA., Nashville, TN., Philadelphia, PA., Queens, NY., Rockville, MD., Silver Spring, MD.

Travel Requirements: Occasional Travel - You may be required to travel for this position

Application Period: August 13, 2020 to September 3, 2020

Salary: Title 21 (AD) Band H, Salary starting at $239,648

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

Special Notes: This position is being filled under an excepted 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 the authority.

Additional information on 21st Century Cures Act can be found here.

Introduction:
This position is located in the Office of Regulatory Affairs (ORA), within the Food and Drug Administration (FDA or the Agency) in Silver Spring, Maryland.

The Food and Drug Administration (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective.

Serve on the frontlines protecting our nation's public health safety within the Office of

Regulatory Affairs (ORA). At ORA, we work in a range of program areas and locations, with 227 offices and 13 laboratories throughout the nation or around the world. Our employees conduct inspections; investigate criminal violations; analyze lab samples; provide administrative services, and much more. Be a part of ensuring that the thousands of products we use every day are safe and effective.

FDA's Office of Regulatory Affairs is the lead office for all agency regulatory inspection activities. ORA supports the six FDA product centers by inspecting regulated products and manufacturers, conducting sample analyses on regulated products and reviewing imported products offered for entry into the United States. In addition to executing its mission through its federal workforce, ORA also works collaboratively with the Centers in developing FDA wide policy on compliance and enforcement and ORA executes the annual commodity work plans. Over 5,000 ORA employees located in district offices, resident posts and laboratories, strategically located throughout the United States perform inspections and investigations (including criminal investigations), wharf exams, sample collections and analyses, and carry out enforcement activities, education and outreach directly to consumers, industry representatives, importers and shippers as well as other stakeholders across the nation. ORA also works with its federal, state, local, tribal, territorial and foreign counterparts to further the agency's mission. ORA is led by the Associate Commissioner for Regulatory Affairs (ACRA).

To view ORA's Vision, Mission, and Values, please visit: https://www.fda.gov/about-fda/office-regulatory-affairs/ora-vision-mission-and-values.

Position Summary:

The OEIO is responsible for providing direction and oversight of field import operations, including conducting field investigations and compliance activities. OEIO coordinates Agency import activities with the U.S. Customs and Border Protection, including the development and institution of joint regulations, procedures, policies, and operations, as well as coordinating activities with other Federal agencies and foreign governments with border responsibilities through interagency agreements, memoranda of understanding, and informal working relationships.

Supervisory responsibilities: The Assistant Commissioner for Import Operations (ACIO) serves as the principal advisor to the ACRA and serves as the supervisor for the Deputy Director for Import Operations Enforcement (DDIOE) and the Deputy Director for Targeting, Analysis and Support (DDTAS), both of whom are in the OEIO Immediate Office.

Duties/Responsibilities:

The ACIO performs substantive work and participates with the ACRA by providing leadership in the development, implementation and evaluation of regulations and policies as they relate to ORA's broad national and international programs and activities to ensure the safety, efficacy, and labeling of FDA-regulated products.

Under the executive direction of the ACRA, the ACIO is a lead for national security intelligence matters involving FDA regulated products offered for import and as such requires top secret clearance.

- Serves as the principle advisor for the FDA global strategy for enforcement of imported FDA regulated products.
- Advises and assists the ACRA and other FDA and ORA senior officials on import operations, and long-range program goals, affecting ORA's 5,300 employees and every Center within FDA.
- Oversees the modernization of the technology used to improve the Import targeting strategy to include system enhancements and screening tools for front line investigators.
- Serves as the FDA principal on the Border Agency Executive Council (BIEC) with U.S. Customs and Border Protection (CBP).
- Oversees the implementation of Food Safety Modernization Act (FSMA) mandates that safeguard the safety of imported FDA-regulated food and feed products.
- Enhances transparency initiatives for sharing compliance information and enforcement data to promote better risk-based product approaches both domestically and internationally.
- Represents and speaks for the ACRA 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 ORA's import program and to resolve complex import regulatory questions and issues that arise.
- Participates with the ACRA, senior officials and others in testifying before Congress on agency regulatory import program and activities.
- Provides leadership and direction on the application of risk management and import program evaluation techniques so that limited resources can provide the most public health promotion/protection at the least cost to the public.
- Negotiates the multi-year Import Program work plan covering both planned and unplanned work between the program manager and the FDA Centers.
- Recommends to the ACRA the annual level of import resources to be reserved in the import allocation for public health emergencies.
- Represents ORA in joint monitoring of the execution of the import work plan and, in consultation with the ACRA.

- 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.

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.

Professional Experience/Desirable Qualifications:

- 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.

Information can be found for individual occupational requirements at the following links:

Miscellaneous Administration and Program Series, 0301

Consumer Safety Series, 0696

Key requirements will include:
To be qualified for this position, you must provide evidence of experience in a managerial capacity. Typically, experience of this nature is gained at or above the GS-15 grade level in the Federal service, or its equivalent with state or local government, the private sector, or nongovernmental organizations.

In addition to specialized experience, applicants must possess the following technical qualifications that represent the knowledge, skills, and abilities essential to perform the duties and responsibilities of the position:

1. Senior level experience as a leader in a complex organization managing, planning, directing, and evaluating multidisciplinary activities of significant scope and effect.

2. Demonstrated ability to build strong working relationships among people and organizations with diverse interests and/or opinions, such as industry, professional, public health or consumer organizations, media, other federal, state, or local agencies, foreign governments and Congress.

3. Experience advising senior officials and implementing organizational policy.

Desirable Education:

- An advanced degree in law, science, public health, management or other related field from an accredited college/university.
- Training, professional development, and outside professional activities that provide evidence of initiative, resourcefulness and potential for effective job performance at a

senior level, and honors, awards, or other recognition for performance or contributions related to the position.

Conditions of Employment:

United States Citizenship is required.

Drug Impact Statement for Top Secret Security Clearance:

The incumbent serves under the executive direction of the Deputy Associate Commissioner for Regulatory Affairs of the Office of Regulatory Affairs in the Food and Drug Administration, and is a lead for national security intelligence matters involving ORA-regulated products and as such requires top secret clearance.

The position requires a Top Secret security clearance and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of highly sensitive, top secret information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HIS plan for a Drug Free Workplace.

Ethics Requirements:

This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

How to Apply: Applicants must submit a current résumé, a current redacted (no personally identifiable information) SF-50 (if applicable), proof of degree or transcripts (if applicable), and a brief (one-page or less) statement explaining your interest and qualifications for this position to ORAExecutiveRecruitment@fda.hhs.gov by September 3, 2020.

For questions please contact Roy Rich, Roy.Rich@fda.hhs.gov, 301-796-9670.

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

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