VACANCY ANNOUNCEMENT

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

Position: Associate Commissioner for Regulatory Affairs (ACRA)

Series: 0601, 0602, 0301

Location(s): Silver Spring, MD

Application Period: November 14, 2019 – November 29, 2019

Salary: Starting at $278,000

Area of Consideration: United States Citizens or Nationals

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:

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.

The FDA's Office of Regulatory Affairs (ORA) is the lead office for all agency field activities. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States. In pursuit of its mission, ORA also works with its state, local, tribal, territorial and foreign counterparts. The mission of the Office of Regulatory Affairs (ORA) is to protect consumers and enhance public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.

The Associate Commissioner for Regulatory Affairs (ACRA) leads FDA's Office of Regulatory Affairs (ORA) and is responsible for protecting consumers and enhancing public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products. Twenty percent of the United States' Gross National Product consists of products regulated by the FDA.

On May 15, 2017, as part of the broader agency Program Alignment initiative, the U.S. Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA) implemented a program-based management structure that aligns staff by FDA-regulated product. This organizational approach replaced the old management structure based on geographic regions.

The products the FDA regulates have become more complex and the global supply chains are more numerous and complicated making the oversight of FDA regulated products even more challenging. Creating distinct product-based and vertically integrated regulatory programs enables the agency to best achieve its objectives, to optimize the coordination and efficiency of the work performed between all FDA Centers, Offices, and ORA, to strengthen accountability and to reduce duplication. The new structure enables staff to work more closely with FDA scientific and technical experts on complex, scientific, manufacturing and other regulatory challenges. Under ORA's program-based management model, there are seven key programs for operations (Biological Products, Bioresearch Monitoring, Human and Animal Food, Medical Devices and Radiological Health, Pharmaceutical Quality, Tobacco and Imports).

The ACRA oversees the regulation of all FDA-regulated products and ensures compliance by:

- Conducting inspections, investigations (civil and criminal) and compliance activities for all FDA-regulated products.
- Providing advice and counsel to FDA leaders regarding medical device, radiological health program operations, and food safety initiatives including emergency response activities.
- Providing advice and counsel to FDA leaders regarding pharmaceutical products field operations and emergency response activities by collaborating with the agency's Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM) on all FDA-regulated pharmaceutical and biopharmaceutical products.
- Providing direction, management and oversight of field import operations, including investigational and compliance activities; and serves as the agency focal point for headquarters/field relationships on all import programs, operations, and problems.
- Providing protection of subjects involved in clinical research for FDA-regulated products and that non-clinical research is conducted according to Good Laboratory Practices (GLP) requirements.
- Conducting inspections of firms and plants producing FDA-regulated products and enforces FDA regulations on the foods and veterinary medicine, medical products, and tobacco industries.
- Oversees a network of 13 laboratories located across the nation whose regulatory science underpins their work.

Position Summary:

This position is responsible for providing the overall executive leadership and direction to the Office of Management (OM); Office of Criminal Investigations (OCI); Office of Partnerships and Operational Policy (OPOP), Office of Communication and Project Management (OCPM), Office of Training, Education and Development (OTED), Office of Human and Animal Food Operations (OHAFO), Office of Medical Products and Tobacco Operations (OMPTO), Office of Enforcement and Import Operations (OEIO), and the Office of Regulatory Science (ORS) as well as the ORA Ombudsman.

The Associate Commissioner for Regulatory Affairs (ACRA) serves as the principal advisor to the FDA Commissioner and other key officials, on regulatory matters having a major impact on Agency-level decisions, policy development, nationwide program execution, as well as the development of both short- and long-range program goals and objectives. The ACRA is charged with managing and directing FDA's nationwide network of commodity-based regulatory operations consisting of investigational, compliance/enforcement, analytical and administrative components, applies a strategic problem-solving approach towards compliance and enforcement that focuses on impacts and results, and uses systematic identification of important problems, strategic planning and prioritization, and effective collaborations with multiple interested parties. The ACRA advises senior FDA officials on achieving compliance with the laws and regulations in order to achieve optimal protection of the nation's public health, serves as the primary strategist and provides executive leadership for developing programs to achieve compliance with FDA's laws and regulations, advises and assists in developing international policies to assure compliance by regulatory industries that provide for the protection of the nation's public health, and independently testifies before Congress on Agency programs and activities.

Additionally, the ACRA advises senior FDA officials on achieving compliance with laws and regulations in order to achieve optimal protection of the nation's public health, assures that the latest scientific tools and techniques are applied in ORA laboratories and in all FDA compliance and enforcement actions, and obtains scientific advice and external peer review to assure that the highest quality science is applied to the protection of the nation's public health.

Supervisory responsibilities: The ACRA is directly responsible to, and functions independently under the broad administrative direction of the FDA Commissioner.

Duties/Responsibilities:

1. **Provides leadership in the development, formulation, implementation, execution and coordination agency activities related to regulatory affairs and to criminal investigative matters**
    - Advises the Commissioner and other senior officials on regulatory issues and compliance

related matters that have an impact on the development and execution of FDA policies and long-term program goals. Provides advice on the regulatory aspects of consumer protection, proposed legislation, implementation of FDA regulations, industry positions and proposals, and precedent cases.

- Advises the Commissioner and other senior officials on criminal investigative matters that have an impact on FDA programs and regulated products.
- Provides leadership in the development of program goals, advancement of programs, and enforcement of laws and regulations designed to protect consumers. Advocates within the agency for prompt and positive action to assure compliance by regulated industries. Promotes and encourages cooperation and collaboration on enforcement strategies and actions to achieve an effective balance between voluntary and regulatory compliance and responsiveness to consumer needs.
- Evaluates the agency's overall compliance efforts and coordinates and collaborates with the product Centers to establish compliance policies to achieve the agency's public health mission. Acts for the Commissioner in analyzing and appraising findings contained in program reports prepared by the agency's organizational components to determine the need for major changes in compliance policy and program goals.
- Contributes to identifying agency needs in terms of national goals, regulatory policy, and program direction to ensure agency objectives are accomplished and commitments are met. Participates in decisions oil the deployment of agency resources to accomplish the agency's legislated responsibilities related to regulatory affairs.
- Advises on the development of FDA international compliance policy and procedures and serves as the agency focal point on regulatory affairs and compliance matters of an international nature.
- Represents the Commissioner in discussions with top level departmental and agency officials, industry representatives, scientific and professional organizations, Members of Congress, other Federal agencies, and state and local governments to secure and provide information on issues and activities related FEA regulatory affairs and criminal investigative activities.
- Provides authoritative advice, interpretations, and recommendations on existing and proposed policies, regulations, legislation and other matters of agency wide significance.

2. **Provides executive and technical leadership through subordinate executives and managers to scientific, professional and support personnel engaged in regulatory affairs and in criminal investigative activities.**
   - Reviews agency compliance activities. Coordinates agency wide evaluation of compliance programs. Evaluates and coordinates all proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives. Provides coordinated direction for agency enforcement and compliance activities. Promotes understanding and compliance with agency's regulatory requirements.
   - Manages and directs FDA's nationwide and international field operations, including criminal investigations. Develops and issues instructions affecting the operations and activities in the regional and district offices. Coordinates development of field

operational programs. Establishes field operations policies, sets priorities, and allocates resources. Evaluates field performance data and accomplishments. Manages and administers the agency's Federal-State programs and policies and coordinates FDA contracts with State and local counterpart agencies.

- Conducts and executes FDA's field operations and activities to ensure that regulated establishments comply with laws and regulations enforced by FDA. Investigates, inspects, and analyzes samples of regulated commodities. Detains violative products, manages recalls, and performs follow up activities. Inspects and determines acceptability of regulated products for entry into US. Applies or recommends use of civil, administrative, and criminal sanctions to protect consumers. Develops and maintains cooperative relationships with Federal, state, and local agencies.
- Evaluates field performance and advises Commissioner of significant problems and trends related to field operations.
- Coordinates agency wide voluntary compliance and industry information activities.

EEO Responsibility:
The incumbent is responsible for furthering the goals of equal employment opportunity (EEO) by taking positive steps to assure the accomplishment of affirmative employment objectives and by adhering to nondiscriminatory employee practices in regard to race, color, religion, sex, sexual orientation, national origin, age, or disability. Specifically, as supervisor, incumbent initiates nondiscriminatory practices and affirmative employment outreach activities for the area under his/her supervision in the following: (1) merit promotion of employees and recruitment and hiring of applicants; (2) fair treatment of all employees; (3) encouragement and recognition of employee achievements; (4) career development of employees; and (5) full utilization of their skills.

The incumbent, in conjunction with his/her supervisor, develops an affirmative employment plan for the area supervised including appropriate objectives and goals; and monitors and periodically assesses progress. Keeps informed of, supports, and communicates to employees EEO policies, plans and programs. Seeks out and utilizes available resources, including appropriate personnel generalists/specialists, EEO specialists, and training resources in conducting these responsibilities.
Incumbent will be appraised on the effectiveness of his/her performance.

<u>Professional Experience/Desirable Qualifications</u>:

- Executive level experience directing a large organization.
- Experience establishing organizational policy, including the implementation of new legislative authorities or other significant mandates.
- Experience managing staff allocation and a fluctuating operating budget for a complex program across the Nation.

- Demonstrated ability to communicate effectively to a large number of staff located in different geographic areas.
- Demonstrated ability and experience coordinating complex work, developing priorities and building coalitions with partners in other organizations.
- An advanced degree in law, science or management from an accredited college or university.
- Held a position showing evidence of leadership responsibility in a regulatory, scientific or other professional organization.
- Experience interacting with the media and with entities that perform oversight activities, such as Congress or the General Accountability Office or a Board of Directors.

Key requirements will include:

- Knowledge of pertinent laws, regulations, policies and precedents.
- Exceptional analytical skills, able to interpret and apply scientific instructions, policies, procedures and guidelines.
- Proven professional experience and stature in their area of expertise, commensurate with the duties of the position being filled.
- Skill in adapting analytical techniques and evaluation criteria to measure program efficiency.
- Demonstrated ability to approach assigned duties in a highly organized, detailed and accurate manner.
- Ability to manage multiple priorities and work in a flexible, dynamic and fast-paced environment.
- Excellent written and oral communication and influence skills, with the ability to inspire confidence and work successfully with diverse audiences.
  Demonstrated strength with organizational management, leadership and team-building.
- Creativity in problem identification and resolution and a relentless drive to accomplish company goals and objectives. A can-do attitude is a must.
- Polished and professional presence with capacity to act as a highly visible representative of the organization.
- Able to travel up to 50%

Desirable Education:

A M.D., D.V.M, Ph.D. or equivalent doctorate in one of the following: biological sciences, microbiology, chemistry, agriculture, natural resource management, basic medical science, physical sciences, life sciences, engineering, or related scientific fields that provide knowledge directly related to consumer safety officer work. Up to 8 semester hours in statistics or course work that includes the principles, theory or practical application of computers or computer programming may be accepted.

Conditions of Employment:

Security Clearance: This 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 HHS 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: Submit resume or curriculum vitae with cover letter by November 29, 2019 to: CuresExecutives@fda.hhs.gov For questions please contact Diane Bazzle at (240) 402-4877. Please reference Job Code: ACRA

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