VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Medical Products and Tobacco Operations (OMPTO)

Position: Assistant Commissioner for Medical Products and Tobacco Operations

Series: 0401, 0601, 0696

Location: Silver Spring, MD

Application Period: November 27, 2019 - December 13, 2019.

Salary: Band G, starting at $197,241.

Area of Consideration: All United States Citizens.

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) is a Federal, science-based regulatory agency with the legislated responsibility to promote and protect the health of the nation's 265 million consumers, in their use of foods, food additives, human and animal drugs, biological products, cosmetics, medical devices, tobacco products and radiation-emitting products and substances. FDA's programs are global in scope and effect, and its activities directly affect and heavily impact on multi-billion-dollar industries, assuring honest and fair dealing in the marketplace, while protecting the public health.

FDA's Office of Regulatory Affairs (ORA) is the lead office for all agency regulatory 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 with the FDA Centers, who develop 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).

The incumbent fully participates with the Associate Commissioner for Regulatory Affairs (ACRA) and the Deputy Associate Commissioner for Regulatory Affairs (DACRA) in providing leadership and managerial direction, through subordinate managers, to ORA's Office of Biologics Products Operations (OBPO), Office of Pharmaceutical Quality Operations (OPQO), Office of Medical Device and Radiological Health Operations (OMDRHO), Office of Bioresearch Monitoring Operations (BIMO), and Tobacco Operations Staff. This executive provides leadership to a field force comprised of specialized districts focusing on medical products and tobacco, including over 1,000 employees engaged in ensuring compliance with FDA laws, rules and regulations for all domestic and imported medical products regulated by FDA.

Leadership for Medical Product and Tobacco Operations

- Manages and directs FDA's nationwide network of field medical product and tobacco operations consisting of investigational, compliance/enforcement, analytical and administrative components.
- Uses strategic problem-solving approach towards medical product and tobacco compliance and enforcement that focuses on impacts and results.
- Uses systematic identification of important problems, risk assessment and prioritization, and effective collaborations with multiple interested parties.
- Coordinates medical product and tobacco compliance and enforcement efforts across partner Centers, i.e., finds ways to assure that individual Center plans are brought into a comprehensive approach.
- Assures consistency of approach across specialized operational program divisions.
- Develops means of assuring consistency in training and credentialing of medical product and tobacco investigators.
- Develops programs to assure consistency of medical product and tobacco safety and efficacy between domestic and imported products.
- Undertakes strategic and risk-based global industry oversight and enforcement using a variety of tools, including inspections, sound regulatory science and policy, risk-based analytics, modern information technology, partnerships with state, federal and global entities, and informal, administrative, civil, and criminal compliance and enforcement measures.
- Provides leadership and guidance for the BIMO initiative by directing and overseeing ORA's participation in the scientific review of the Bio-Research Monitoring Program which includes all FDA Centers and ORA to evaluate its scope and scientific relevance to current needs.

Regulatory

- Serves as the primary strategist and provides executive leadership for developing programs to achieve compliance with FDA's laws and regulations that pertain to medical products and tobacco.
- Advises and assists in developing international medical product and tobacco policies to assure compliance by regulatory industries that provide for the protection of the nation's public health.
- Provides knowledge/input into the development of risk-based nationwide inspection and compliance programs and enforcement strategies to achieve work efficiencies by focusing allocated resources and targeting the safety and security of medical products and tobacco.

Public Health/Scientific

- By fully participating with the Director of the Office of Regulatory Science (ORS), assures that the latest scientific tools and techniques for medical product and tobacco analysis are applied in ORA laboratories and in all related FDA compliance and enforcement actions.
- Develops innovative programs for alternative means of obtaining regulatory compliance and protection of the nation's public health that emphasize problem solving, risk assessment, prioritizing results, collaboration and leveraging FDA resources.
- Represents FDA medical product and tobacco regulatory programs to the general public and FDA's specific regulatory constituencies, which include compliance/enforcement /operational activities such as seizures, civil money penalties, and injunctions; conducting foreign and domestic pre-market and post-market inspections of human drugs, biologics, tobacco products and medical

devices.
- Participates with the ACRA and DACRA in managing ORA's geographically dispersed workforce and laboratories strategically located throughout the U.S.; directs the nationwide regulatory workforce in enforcing compliance with the Federal Food, Drug, and Cosmetic Act and multiple other federal laws and regulations that apply to regulated products.

Desired Skills, Experience:

- Advanced knowledge of Medical Products and Tobacco.
- Demonstrated strength with organizational management, leadership and team-building and the ability to manage multiple priorities and work in a flexible, dynamic and fast-paced environment.
- Executive level experience in managing a diverse and geographically disbursed organization, including budgeting, capital investments and human resources.
- Executive level experience in developing and implementing an organizational vision for a large complex and diverse organization that integrates broad program goals, priorities, and balances change and continuity.
- Experience establishing operational policy, including the implementation of new legislative authorities or other significant mandates.
- An advanced degree in law, science, public health, management or other related field from an accredited college/university.
- 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.
- Experience formulating and establishing strategies and influencing strategy and policy relating to compliance, enforcement, or imported medical product and tobacco activities.

Qualifications:

- Professional experience and stature in their area of expertise commensurate with the duties of the position being filled.
- Demonstrated managerial experience in diverse organizations.
- Excellent oral and written communications skills.
- Strong analytical skills.

General Natural Resources Management and Biological Sciences Series, 0401

Individual Occupational Requirements

Basic Requirements

1. Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.

or

2. Combination of education and experience: Courses equivalent to a major, as shown in A above, plus appropriate experience or additional education.

General Medical and Healthcare Series, 0601

Individual Occupational Requirements

Basic Requirements

Education

Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education(external link) at the time the degree was obtained.

Consumer Safety Series, 0696

Individual Occupational Requirements

Basic Requirements
The education must have been obtained at a college, university, or an accrediting body recognized by the Secretary, U.S. Department of Education (external link) at the time the degree was obtained.
Applicants must meet one of the following requirements.

A. A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work.

The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.
OR

B. Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in paragraph A above, plus appropriate experience or additional education.

Experience
To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the grade level of the position. Qualifying experience involves enforcing laws and regulations to protect consumers from foods, drugs, cosmetics, fabrics, toys, equipment, and household products that are defective, dangerous, impure, unwholesome, ineffective, or improperly or deceptively labeled or packaged.

Application Procedures:

Applications will be accepted from all qualified internal and external applicants. Please send letter of interest addressing your experience in the major duties and responsibilities of the position, CV and bibliography, SF-50 for current federal employees only, transcript (with foreign credentials evaluation, if applicable) to the ORA Executive Recruitment Committee, ORAExecutiveRecruitment@fda.hhs.gov. Applications will be accepted on through December 13th.

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

Conditions of Employment:

U.S. Citizenship is required

How You Will Be Evaluated: A review of your resume and supporting documentation will be made to determine if you are qualified for this job based on how well you meet the desired qualifications above. If you are referred to the hiring manager for consideration, you may be further evaluated based on an interview.

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 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 http://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/default.htm.

Security and Background 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.
Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

Drug Impact Statement for Top Secret Security 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.

The incumbent serves under the executive direction of the 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.

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 action objectives and by adhering to non-discriminatory employee practices regarding race, color, religion, sex, national origin, age, or handicap. Specifically, as a manager, incumbent initiates non-discriminatory practices and affirmative action for the area under his/her supervision in the following: 1) merit promotion of employees and recruitment and hiring of applications; 2) fair treatment of all employees; 3) encouragement and recognition of employee achievements; 4) career development of employees; 5) full utilization of their skills.

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.

Benefits: As a new or existing federal employee, you and your family may have access to a range of benefits. Your benefits depend on the type of position you have - whether you're a permanent, part-time, temporary or an intermittent employee. You may be eligible for the following benefits, however, check with your agency to make sure you're eligible under their policies. You can find information about each program at https://www.opm.gov.