Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Associate Commissioner for Regulatory Affairs (ACRA)

Application Period: *5/31/2023-7/26/2023*

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Associate Commissioner for Regulatory Affairs (ACRA)

Series: This position can be filled in a variety of series to include 301, 601, 602 and 701 series

Location(s): Silver Spring, MD

Work Schedule: Full Time

Salary: Starting at $301,825

Cures Band(s): Band I

Full Performance Band Level: Band I

Travel Requirements: 25%

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

This position is being filled under a stream-lined hiring authority, Title 21 of the United States Code (21 US Code 379d-3a) as amended by the 21st Century Cures Act of 2016, section 3072 and the Consolidated Appropriations Act of 2023, Section 3624. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of this authority.

Introduction

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

The FDA's Office of Regulatory Affairs (ORA) is the lead office for all agency field activities. In January 2023, the FDA announced a proposal for a unified Human Foods Program, which includes a restructuring of ORA to support the FDA organization as a whole. This model, which would be implemented following a formal reorganization process, would better integrate ORA with all FDA regulatory programs by:

- Improving the risk prioritization and public health impact of the FDA's field activities. ORA's goals will be set by the regulatory programs and take a more prevention-based approach to food safety inspections as envisioned in the FDA Food Safety Modernization Act.

- Modernizing the FDA's field activities. ORA will focus on strengthening and modernizing its core operations and increase its specialization in concert with the regulatory programs.

- Creating operational efficiencies. Certain ORA functions will be realigned into a unified Human Foods Program and other regulatory programs or with agency-wide services to further enhance operations.

This will optimize ORA operations in line with the FDA's public health and prevention-oriented goals.

Functional Duties and Responsibilities

The ACRA is responsible for providing the overall executive leadership and direction to ORA staff. The ACRA serves as the principal advisor to the FDA Commissioner and other key officials on field-based 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 develops and implements effective operational management strategies that can efficiently adapt to continuously changing circumstances and align with Agency-level goals and objectives. The ACRA advises senior FDA officials on achieving industry compliance with the laws and regulations to achieve optimal protection of the nation's public health; develops strategies and provides executive leadership for developing programs to achieve compliance with FDA's laws and regulations; and advises and assists in developing international policies to assure compliance by regulatory industries that provide for the protection of the nation's public health.

Duties/Responsibilities

- Provides leadership for change management and organizational evolution in support of FDA enterprise operational changes, including the proposal for a unified Human Foods Program, and leverages proven ability to implement strategies to lead workforce through major organizational change and effectively improve and monitor the environment for cultural transformation.

- Partners with FDA Center Directors and other FDA leaders to develop and implement innovative operational policies that enable close collaboration among internal stakeholders and decision makers and provides executive leadership in efforts to coordinate cross-cutting policy activities. Works in close collaboration with the Deputy Commissioner for Human Foods to coordinate and support Human Foods Program activities.
- Sets priorities and goals related to professionalization of FDA workforce and establishes education and training programs related to FDA-regulated commodities.
- Promotes innovation to build a more robust regulatory program that promotes public health and is responsive to emerging challenges and opportunities that are often presented in ever-changing, rapidly evolving, and emergency response environments. Fosters transparency, timeliness, and predictability in decision-making, with a preference towards action.
- Leverages expertise in logistics, preferably on a national or global scale, to establish innovative approaches to ensure operational readiness and continuity of regulatory programs in a constantly changing environment.
- Designs and implements strategies that build and enhance inspectorate workforce capacity to ensure operational readiness and enable agile responses to emerging situations. Relies on a deep understanding of data analytics to facilitate the integration of risk into decision-making related to inspections.
- Directs work of ORA activities to develop innovative collaborations and positive working relationships with external partners and stakeholders, both domestically and internationally, serving as an outward-facing ambassador for the Agency's work. As designated by the Commissioner, represents the Agency in meetings, conferences, and Congressional engagements and establishes and maintains effective relationships with top level FDA and HHS officials, national/international industry representatives, Members of Congress, counterparts from other Federal, State and local government agencies, foreign government representatives, academia, consumer and other groups to secure, exchange and provide information concerning operational and regulatory policy, science, and innovation issues.
- Leverages financial acumen to implement cost effective regulatory strategies and efficiently manage ORA resources.

Supervisory Responsibilities: The incumbent of this position is directly responsible to, and functions under the broad administrative direction of, the Commissioner of Food and Drugs. Incumbent is expected to work with an exceptional degree of independence and initiative to reach conclusions and solve problems specific to their organization. Technical advice and

recommendations regarding inspections, investigations, and field-based regulatory affairs are normally accepted without significant changes. Work is reviewed for accomplishment of broad objectives.

This position is designated as an SES Equivalent position and is covered under the FDA Title 21 Executive Performance Management System and identified as a public filing position for ethics purposes.

Organizational Management: Manages a cross-cutting organization, including its respective components.

Program Management: Runs ORA reporting directly to the Commissioner and is responsible for overseeing all aspects of ORA operations. Identifies outcomes needed to achieve its mission goals. Establishes and directs program outcomes for an FDA Center. Establishes and directs organizational objectives that encompasses the agency's public health mission, operational and human capital strategies.

Resource Management: Possesses highest resource authority within ORA. Allocates resources according to Agency mission in collaboration with other Agency components. Coordinates and directs the allocation of resources in alignment with the strategic priorities of various Agency counterparts to appropriate components, ensures that allocation of resources is utilized in accordance with the identified priorities of various Agency components, and contingent upon those allocated/shared by respective Centers and Programs. Delegates resource authority as appropriate. Serves as accountable official for resource management and reporting for ORA operations.

Personnel Performance Management: Counsels and rates immediate subordinates.

Human Capital Management: Identifies organizational capabilities needed to achieve ORA mission goals.

EEO responsibilities: 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 in regard to 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. Specifically, as a manager, the incumbent initiates nondiscriminatory practices and affirmative action for the Center in the following: (1) merit promotion of employees and recruitment and hiring; (2) fair treatment of all employees; (3) encouragement and recognition of employees' achievements; (4) career development of employees; and (5) full utilization of their skills.

Qualifications

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following qualifications. Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not automatically be excluded from consideration for this position.

To be placed into a Cures position, candidates must meet the following criteria:

1. Experience in Scientific, Technical, and/or Professional Fields

2. Qualified and Outstanding Candidates

a. ***Qualified*** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.

b. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

Position's Desired Skills, Experience and Education:

- 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
- Demonstrated ability to communicate effectively both internally and externally to a large number of staff located in different geographic areas
- Demonstrated ability and experience coordinating complex work and 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
- Talent for leading cultural and organizational change management efforts

Education Requirement:

Additional Info: This position is being filled under the 21st Century CURES Authority, under Band I (Executive level). Applicants applying for this position, do not need to hold an active medical license.

General Health Sciences Series, 0601

Degree: 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 at the time the degree was obtained.

Public Health Program Specialist Series, 0602

Degree: Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent from a school in the United States or Canada. This degree must have been accredited by the Council on Medical Education of the American Medical Association; Association of American Medical Colleges; Liaison Committee on Medical Education; Commission on Osteopathic College Accreditation of the American Osteopathic Association, or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Veterinary Medical Science Series, 0701

Degree: Doctor of Veterinary Medicine (DVM) or equivalent degree, i.e., Veterinary Medical Doctor (VMD), obtained at a school or college of veterinary medicine accredited by the American Veterinary Medical Association Council on Education (AVMA).

This position may also be filled in the following series: **0301- Miscellaneous Administration & Program Series.** There is no education requirement for this series, but experience related to the position will be evaluated.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. 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 FDA employee, you are not exempt from transcript requirements.

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

Conditions of Employment

• U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.

• Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.

• Applicants must meet all qualification requirements by the closing date of this announcement.

• 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.

• One-year probationary period may be required.

• Financial Disclosure is required.

• Ethics Clearance is 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 at a later time.

• This position is designated as an SES Equivalent position.

Drug Impact Statement for Top Secret/SCI Security Clearance

This position is special-sensitive and requires the incumbent to have access to highly classified data, documents, facilities and/or materials related to national security, thus demanding the highest degree of public trust, and requiring the incumbent to possess and maintain a Top Secret/SCI security clearance. 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 DHHS plan for a Drug Free Workplace.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements:

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 Clearance Requirements

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.

Equal Employment Opportunity

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

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.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

How to Apply

Submit resume or curriculum vitae with cover letter by **11:59pm on 7/12/2023** to: CuresExecutives@fda.hhs.gov. Please reference Job ID in subject line of email: **OC-ACRA-2023-02**

Announcement Contact

For questions, please contact CuresExecutives@fda.hhs.gov. Please reference Job Reference ID in subject line of email: **OC-ACRA-2023-02.**

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