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

Application Period: 01/11/2024 – 02/01/2024

Area of Consideration: This announcement is open to FDA employees only. 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: Deputy Associate Commissioner for Regulatory Affairs (DACRA)

Series: AD - 0696, 0301

Location(s): Silver Spring, MD

Salary: Starting at $259,391

Work Schedule: Full Time

Title 21 Band: Band H, Pay Table 4

Full Performance Band Level: Band H

Travel Requirements: Up to 25% travel

Bargaining Unit: 8888

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, 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 this authority. Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

Introduction

The Food and Drug Administration (FDA) 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 United States are adequately, truthfully and informatively

labeled and safely and properly stored, transported, manufactured packaged and regulated. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

The mission of the Office of Regulatory Affairs (ORA) is to protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products. To view our ORA Vision, Mission, and Values please visit: https://www.fda.gov/about-fda/fda-organization/office-regulatory-affairs.

The ORA is at the forefront of building a public health safety net for today's complex, global regulatory environment. ORA professionals work in a range of program areas and locations, with 227 offices and 12 laboratories throughout the United States. As the lead office for all FDA field activities, ORA serves as the agency's direct connection with regulated industry through a) inspections of firms and plants producing FDA-regulated products, b) investigations of consumer complaints, emergencies and criminal activity, c) enforcement of FDA regulations, d) sample collection and analysis, and e) review of imported products.

Duties/Responsibilities

The DACRA serves as the principal advisor to and surrogate for the Associate Commissioner for Regulatory Affairs (ACRA) on the full range of ORA activities including enforcement (regulatory and criminal), implementation of new laws and regulations; overall strategic planning and prioritization; strategic projects and initiatives; and document clearance. In this capacity, the incumbent shares fully the responsibility for planning, coordinating, directing, and evaluating activities of the ORA.

In conjunction with the ACRA, the DACRA directs ORA employees engaged in regulatory, enforcement, compliance activities and scientific programs which lead to greater public health protection. The DACRA is responsible for providing long range strategic direction for ORA policies and programs including the implementation of the Food Safety Modernization Act, the FDA Reauthorization Act (FDARA), the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act and the Generic Drug User Fees Act. This includes the delegated authority to, and accountability for, making managerial and technical decisions required for successful program execution, administration, and management.

Supervisory Responsibilities: The DACRA is directly responsible to, and functions independently under the broad administrative direction of the ACRA.

Represents the ACRA and initiates, establishes, and maintains cooperative and collaborative relationships with International/Federal/State/Local governmental agencies, academic communities and others and participates in meetings and conferences with top level Office,

Agency or departmental officials, industry representatives, program directors, senior scientific and subject matter specialists, representatives from counterpart executive governmental departments, independent agencies, and others.

Balances needs identified across the Agency with resource availability, working with the other Centers and senior officials to address highest priorities with appropriate consideration to the entire set of needs.

Provides staff leadership and direction by performing substantive activities related to the development, administration, execution and coordination of nationwide programs and policies.

Manages and directs over 5,000 employees in 250 locations under a complex budget of over $1 billion, engaged in regulatory, enforcement, compliance activities and scientific programs, which leads to greater public health protection.

Reviews and evaluates project proposals and plans submitted by ORA programs and offices in terms of soundness of scientific/technical reasoning, sufficiency of project proposal, relative priorities, availability of resources and anticipated results.

Responsible for carrying out the full range of responsibilities and acts with full authority over the total work of ORA during the ACRA's absence or unavailability.

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.
- Financial Disclosure may be required.
- One year supervisory probationary period 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 at a later time. 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.
- 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).

Qualifications

To be placed into a Title 21 position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
    a. ***Qualified*** applies to all candidates for Title 21 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.

In order to qualify for this Title 21 position, the candidate(s) must meet the following **required** 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 be excluded from consideration for this position.*

Education Requirement: Candidates must qualify for one of the following series:

Consumer Safety Series, 0696

Miscellaneous Administration and Program Series, 0301

Desirable Education: An advanced degree in law, science or management from an accredited college or university.

Desired Professional Experience:

- 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.
- Held a position showing evidence of leadership responsibility in a regulatory, scientific, or other professional organization.

- Experience advising senior officials and interacting with the media and with entities that perform oversight activities, such as Congress or the General Accountability Office or a Board of Directors.

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.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Top-Secret

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 accommodation to have an equal opportunity to apply for a job. An employee with a disability needs accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request 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

Applications will be accepted from all qualified internal applicants. Please send letter of interest addressing your experience in the major duties and responsibilities of the position, resume/CV and bibliography and redacted SF-50 to the ORA Executive Recruitment and Scientific Staffing Committee, ORAExecutiveandScientificRecruitment@fda.hhs.gov. Applications will be accepted through February 1, 2024. Please reference job ID: **7/2 – DACRA** in the email subject line.

Announcement Contact

For questions regarding this Title 21 position, please contact Oraexecutiveandscientificrecruitment@fda.hhs.gov

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

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