



TITLE 21 VACANCY ANNOUNCEMENT

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

Position: Deputy Associate Commissioner for Regulatory Affairs (DACRA)

Series: 0301, 0696

Location(s): Silver Spring, MD (White Oak Campus)

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

Application Period: April 28, 2020 to May 20, 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 FDA is the regulatory, scientific, public health and consumer protection agency responsible for ensuring 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 for tobacco product regulation in order to decrease the tremendous toll of disease, disability, and death caused by tobacco use in the United States. FDA's programs are national in scope and effect, global in operations, and the Agency's activities have a direct and significant impact on protecting the health and safety of American consumers. The work of the Agency is carried out by a staff of over 12,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

ORA is the lead office for all Agency field activities. ORA conducts inspections and investigations (civil and criminal) of regulated products and manufacturers, conducts sample analysis 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. ORA is led by the Associate Commissioner for Regulatory Affairs (ACRA) who directs and evaluates the overall management and capabilities of the Agency's field organization.

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 incumbent serves as the Deputy Associate Commissioner for Regulatory Affairs (DACRA) and principal advisor to the Associate Commissioner for Regulatory Affairs (ACRA) on the full range of ORA's 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 addition, as the principal policy advisor to and spokesperson for the ACRA, the incumbent provides staff leadership and direction by performing substantive activities related to the development, administration, execution and coordination of nationwide programs and policies.

Supervisory responsibilities: The DACRA assists in managing ORA. The DACRA exercises delegated authority over the programs and exercises final authority on personnel actions and organization design proposals from subordinate positions.

Duties/Responsibilities:

Serves as principal advisor to and surrogate for the ACRA on the full range of ORA's activities including; enforcement (civil and criminal); regulatory science implementation; import operations; global/federal/state collaborations; implementation of new laws and regulations; and overall strategic planning and prioritization. Is the principle policy advisor to and spokesperson for the ACRA.

Provides long range strategic direction for ORA policies and programs including the implementation of the Food Safety Modernization Act (FSMA), the FDA Reauthorization Act (FDARA), the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, and the User Fee programs. This includes the delegated authority to, and accountability for, making managerial and technical decisions required for successful program execution, administration and management.

Shares fully the responsibility for planning, coordinating, directing and evaluating activities of the ORA. Coordinates inter-office/division/staff support of legal and administrative actions/sanctions/proceedings arising from agency-initiated enforcement actions related to regulated products. Applies thorough and comprehensive program knowledge and keeps abreast of scientific and technological developments which are related to or have bearing on regulatory activities.

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.

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:

- Professional experience and stature in their area of expertise commensurate with the duties of the position being filled.
- Excellent oral/written communications and analytical skills.
- Executive level experience directing/managing a large organization including 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 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
- 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.

Key requirements will include: To be qualified for this position, your résumé must reflect experience in a managerial capacity with responsibility for providing supervisory direction to a large and diverse organization responsible for promoting economy, efficiency, and effectiveness in the administration of programs and operations and preventing and detecting fraud and abuse in such programs and operations. This experience must be evidenced by sophisticated analytical skills, superior written and oral communication skills, good judgment, and experience in interacting with government and non-government officials. 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. At this level, you would have typically been responsible for planning, directing, and evaluating work that included managing and/or supervising other managers. You must demonstrate in your résumé, significant achievements, increasing levels of responsibility as a manager, and a solid record of successful professional performance.

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

Conditions of Employment: *U.S. Citizenship is required, *Ability to obtain top-secret security clearance, *Ethics pre-clearance is required.

Security Clearance: 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)

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: 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.

For questions please contact Kathleen Davis at, Kathleen.Davis1@fda.hhs.gov, 240-704-0436.

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

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