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)
Supervisory Regulatory Counsel

Application Period: 11/29/2023 - 12/13/2023

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: Supervisory Regulatory Counsel

Series: AD-0301

Location(s): Remote Eligible

Salary: Starting at $155,700

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: Up to 25% travel

Bargaining Unit: This is a non-bargaining unit position.

Relocation Expenses Reimbursement: Incentives may be authorized; however, this is contingent upon availability of funds. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 4 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives may include recruitment or relocation incentives in accordance with FDA, Title 21 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 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 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/office-regulatory-affairs/ora-vision-mission-and-values.

The Office of Regulatory Affairs (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.

This position is located in the Office of Regulatory Affairs (ORA), Office of the Associate Commissioner for Regulatory Affairs (ACRA) Immediate Office. The ACRA oversees the approximately 5,000 ORA staff working in Field locations around the United States and throughout the world. ORA partners across FDA product Centers to protect public health through inspections, investigations, and import activities, among other areas. This role serves as a recognized government-wide expert in matters related to his or her area of responsibility and is frequently called upon to advise others concerning FDA statutes and regulations and ORA operational policy.

Duties/Responsibilities

The incumbent serves as an expert and authority on FDA legal issues and policies as they impact ORA operations, advising congressional oversight and interactions with government agency auditors, international issues, and other Agency initiatives. The employee performs duties that include resolving a broad range of operational and technical issues concerning the application of any of FDA's enabling legislation, pertinent regulations, and/or general legislation affecting the operation of the Federal government. The incumbent provides regulatory expertise on

proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives to the ACRA and staff. Performs analyses on public policy decisions that could have a potential impact on ORA. The incumbent provides authoritative guidance to the ACRA concerning FDA policies, programs and procedures, as well as formulates ORA's position on matters involving congressional oversight, emergency response, international issues, and Agency initiatives. Assignments are often complicated by the need to research complex or controversial issues of wide public interest and collaborate across ORA and product Centers to develop the appropriate resolution or response.

- Develops policies and programs involving the most complex and highest priority matters affecting policies implemented by ORA. Drafts or critically reviews documents embodying legislative policy and program proposals and decisions on these products. These documents, which, authoritatively state or interpret ORA or FDA policy, receive minimal review by the ACRA.
- Drafts and/or reviews proposals for new regulations and policy statements involving his or her area of expertise. These regulations and policy statements often result from the need to implement new legislation or from new interpretations of existing legislation. These regulations and policy statements are broad in scope and generally affect either an entire or a significant sector of the organization.
- Oversees the preparation of Congressional Testimony responses to Congressional inquiries, correspondence from the regulated community and other interested persons on issues that are industry-wide in scope or have broad health implications and that concern precedent- setting interpretations of FDA policy.
- Reviews petitions raising issues that could have an industry-wide effect or a far-reaching impact on ORA. Develops a course of action and drafts or coordinates the drafting of responses to such petitions.
- Makes presentations at conferences and professional meetings in the U.S. and overseas before the regulated industry and others on implementation of policies and/or initiatives that are being undertaken by ORA and could impact them. These presentations communicate current policy developments at the agency and serve as a means for soliciting the concerns and criticisms of the regulated industry. The Supervisory Regulatory Counsel/Policy Analyst sometimes serves at these meetings as the sole representative of FDA and/or the ACRA.
- Advises other offices in ORA on procedures and methods for implementing new authorities and mandates, interpreting existing regulations, and providing guidance regarding the legal sufficiency and procedural adequacy of proposed policy statements and policy initiatives.

Supervisory responsibilities: This position is a first line supervisor of the ACRA's Immediate Office with supervisory responsibilities to include:

- Plans work to be accomplished by subordinates, set and adjust short-term priorities, and prepare schedules for completion of work.

- Evaluates work performance of subordinates.
- Gives advice, counsel, or instruction to employees on both work and administrative matters.
- Interviews candidates for positions in the unit; recommends appointment, promotion, or reassignment to such positions.
- Hears and resolves complaints from employees, referring group grievances and more serious unresolved complaints to higher level supervisor or manager.
- Effects minor disciplinary measures, such as warnings and reprimands, recommending other action in more serious cases.
- Identifies developmental and training needs of employees, providing or arranging for needed development and training.
- Finds ways to improve production or increase the quality of the work directed.

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 supervisory probationary period may be required.
- Financial Disclosure 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.

Qualifications

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

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates

   a. **Outstanding** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.
   b. **Qualified** applies to all candidates for Title 21 appointments.

To qualify for this Title 21 Cures 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: A law degree, specifically a LL.M. or J.D. The degree must be from an accredited program or institution.

OR

Experience: Comparable regulatory experience focused on interpreting laws, rules, regulations, or policies; or develop or analyze regulations and policies for regulated products.

Position's Desired Skills, Experience: The U.S. Food and Drug Administration is a highly visible, collaborative, and impactful organization. As such, this individual must be flexible to operate in a driven culture and capable of exercising good judgment and decision-making capabilities in times of ambiguity. A strong candidate can readily demonstrate:

- Training and experience that demonstrate excellent legal and policy analysis skills and attention to detail.
- Demonstrated ability to communicate well orally and in writing.
- Solid understanding of FDA oversight of regulated industry including issues related to inspections, investigations and other oversight activities.
- Demonstrated ability to identify and analyze problems, determine, and weigh the relevance and accuracy of related information, evaluate solutions, and make recommendations with supporting rationales.
- Demonstrated ability to work successfully with staff at all levels of the organization and varying levels of domain expertise, and to collaborate across boundaries to build strategic relationships and achieve high-quality, coordinated results.
- Demonstrated ability to work independently and as a contributing collaborative team member.
- Demonstrated ability to organize time effectively, determine priorities, and move work forward efficiently.

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: 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.

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

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

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.

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

How to Apply: Applications will be accepted from all qualified internal and external applicants. Please email letter of interest addressing your experience in the major duties and responsibilities of the position, resume, redacted SF-50 (redact SSN and DOB; for federal employees only), transcript (with foreign credentials evaluation, if applicable) to the ORA Executive Recruitment and Scientific Staffing Committee: oraexecutiveandscientificrecruitment@fda.hhs.gov.

IMPORTANT: You must reference Job ID in the email subject line: **7/2-Supervisory Regulatory Counsel**

Applications will be accepted through **December 13, 2023**.

Announcement Contact

For questions regarding this Cures position, please contact oraexecutiveandscientificrecruitment@fda.hhs.gov.

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

FDA is an equal opportunity employer.