Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Immediate Office
Senior Science Advisor

Application Period: January 26, 2024 - February 4, 2024

Area of Consideration: Open to FDA employees only. US 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: Senior Science Advisor

Series: AD - 0696

Location(s): Silver Spring, MD

Salary: Starting at $181,551

Work Schedule: Full Time

Cures Band(s): Pay Table 1, Band F

Full Performance Band Level: F

Travel Requirements: Up to 25% travel required.

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 or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animal, tobacco, 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 multibillion 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/fda-organization/office-regulatory-affairs.

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.

The Senior Science Advisor (SSA) reports to the Associate Commissioner for Regulatory Affairs (ACRA) and serves as the principal advisor to the ACRA and other key officials on regulatory matters having a major impact on Agency-level decisions, policy development, nationwide program execution, and short- and long-range program goals and objectives.

Duties/Responsibilities

The SSA serves as the principal authority to the ACRA in the formulation and/or prioritization of program goals, objectives, and broad operating policies, functioning as a representative of the ACRA in coordinating and establishing the Agency position on selected policies, issues, and problems. Additional duties include, but are not limited to:

- Carries out special projects such as preparing issue and decision papers relating to ORA programs and plans for use in briefings for a variety of officials, including White House and OMB officials and for getting decisions on major policy issues.
- Works with members of senior program management staff to prepare short- and long-range goals, objectives, and operational plans for carrying out the ORA public health activities.
- Identifies and analyzes issues and their impact on public health policies as they relate to regulatory programs. Consults on, monitors, and measures the outcome of these programs through studies which evaluate the effectiveness of project activities in meeting the Agency and ORA needs. Leads the design, implementation, and analysis of
- significant collaborative studies with State and local, national, or international policy or

program implications.
- Advises on planning, policy, budgeting, scientific legislative, and regulatory framework for the ORA's public health programs and serves as the chief analyst with the responsibility for determining the effectiveness of these programs and the ORA's operations.
- Participates in meetings and conference with high level Agency officials, DHHS, Congressional and other State and Foreign officials to identify and discuss issues and problems of mutual interest, secures, and provides information related to matters of interest to the ACRA, presents positions, conclusions, and alternatives, obtains agreement and concurrence, and develops courses of action to avoid, eliminate, or mutually resolve immediate, anticipated, or potential problems.

Supervisory Responsibilities: This is an advisory role. The incumbent provides scientific guidance and direction for ORA senior leaders in the areas of pharmaceuticals, medical devices, radiological health, biologics, bioresearch monitoring, tobacco, cosmetics, and human and animal food products in coordination with the Office Director and assists in identifying gaps in scientific competencies.

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 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 up to 25% travel.

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.

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: The education must have been obtained at a college, university, or an accrediting body recognized by the Secretary, U.S. Department of Education at the time the degree was obtained. For more information please see: OPM Occupational Series Qualification Requirements.

Candidate must qualify for the following series: Consumer Safety Series 0696

Desired Professional 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:

- Mastery knowledge of all the major FDA programs and the industries regulated by those programs and a comprehensive knowledge of the legislation, laws, and regulations.
- Mastery knowledge of the various sciences and technologies which apply to the products regulated by the Agency.
- Ability to gauge the effort at hand, to select what needs to be done, recognizing the impact in terms of risks involved; ability to accomplish work through others at all necessary levels within the agency and in other federal and international organization to achieve appropriate and timely support.
- Ability to analyze complex and sensitive regulatory issues involving numerous variables; develop and appraise alternative solutions; and recommend and take appropriate courses of action in relation to agency regulatory counterparts.
- Proficiency in negotiating skills sufficient to achieve consensus on agency and inter-agency positions' resolve differing points of view between various organizations; in dealing with representatives of foreign governments, achieve compromises that satisfy the foreign government while meeting FDA's goals. Proven professional experience and stature in their area of expertise, commensurate with the duties of the position being filled.
- Ability to communicate in a highly effective matter in writing and in person-to-person contacts; ability to deal effectively with others in a leadership capacity. Ability to work

effectively and highly independently under the pressure of very tight timeframes and to meet deadlines.

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

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, detailed resume and bibliography, redacted SF-50, transcript (with foreign credentials evaluation, if applicable) to the ORA Executive Recruitment and Scientific Staffing Committee, oraexecutiveandscientificrecruitment@fda.hhs.gov. Applications will be accepted through February 4, 2024. Please reference Job ID: **2-Senior Science Advisor, OACRA** in the subject of the email.

Announcement Contact

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

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