Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Commissioner (OC)
Office of the Chief Scientist (OCS)
Office of Counterterrorism and Emerging Threats (OCET)

Application Period: February 6, 2023 – February 24, 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: Regulatory Counsel

Series: AD-0301

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

Salary: Starting at $112,015

Work Schedule: Full Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

Bargaining Unit: 8888

Relocation Expenses Reimbursement: Relocation will not be paid

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 animals, tobacco and radiation emitting devices safe, and effective.

The mission of the Office of the Chief Scientist (OCS) is to provide strategic leadership, coordination, and expertise, supporting scientific excellence, innovation, and capacity to achieve FDA's public health mission. The mission of the Office of Counterterrorism and

Emerging Threats (OCET) within OCS is to promote health security and protect the nation and the international community from public health threats, including acts of terrorism, epidemics, and disasters.

Duties/Responsibilities

The incumbent is a subject matter expert, responsible for providing regulatory, legal and policy matter expertise to advise and support program function within OCET and OCS.

- Advances Medical Countermeasure Initiative (MCMi) program by helping to ensure that U.S. laws, regulations, and policies help support preparedness and response for potential chemical, biological, radiological, nuclear (CBRN) and emerging disease threats.

- The incumbent handles highly complex and difficult assignments of national scope and significance. The incumbent assumes responsibility for ensuring that Agency regulations and policies related to matters concerning global health security, counterterrorism, and emerging threats (including policies and procedures to facilitate the development and availability of medical countermeasures (MCMs) are consistent with statutory requirements and that they are justified to advance FDA's public health mission.

- Utilizes regulatory, legal, and policy experience to review and evaluate proposed regulations, policy documents, regulatory actions, and inquiry responses, including Congressional inquiries, that are highly complex and difficult assignments of national scope and significance.

- Develops, drafts, and critically reviews procedurally sound policies and program proposals and decisions in support of Agency activities related to matters concerning global health security, counterterrorism, and emerging threats (including policies and procedures to facilitate the development and availability of MCMs), FDA-related legislation, regulation, guidance documents and interagency documents related to such issues. Convenes and leads workgroups, as necessary, to respond to the development, interpretation and application of such policies and procedures.

- The incumbent consults with staff at all levels of the Agency on issues within area(s) of responsibility to identify areas of disagreement within the FDA such as between Centers and other units of FDA, to resolve disagreements using decision memoranda or through meetings, and to articulate any policy consensus reached through this process.

- Works with FDA offices and Federal partners to implement consistent policy approaches to facilitate the development and availability of MCMs, including through the implementation of FDA's Emergency Use authorities. Works with medical Center subject matter experts and legal counsel to ensure that use of such authorities are consistent and legally appropriate. Drafts documents related to Emergency Use Authorization, including Federal Register Notices, and replies to correspondence from stakeholders, including public health officials, and other interested persons on issues that are industry-wide in scope or have broad health implications related to interpretations of FDA's Emergency Use authorities.

- As assigned by the Director of MCM Regulatory Policy, incumbent represents the Agency in liaison activities, meetings and working groups. Works with FDA offices and Federal partners to implement consistent policy approaches on activities related to matters concerning global health security,

counterterrorism, and emerging threats (including to facilitate the development and availability of MCMs.

- Makes presentations at conferences and professional meetings before the regulated industry, public health and other government officials, and the medical/scientific community on on issues within area(s) of responsibility. These presentations communicate current policy developments at the Agency and serve as a means of eliciting and alleviating the concerns and criticisms of the regulated industry and FDA government-partners in the MCM enterprise. The incumbent may serve at these meetings as the sole representative of FDA.

- Provides guidance and/or training to regulatory specialists and other professionals within FDA and with Federal, state, local government colleagues external to FDA on matters relating to global health security, counterterrorism, and emerging threats (including policies and procedures to facilitate the development and availability of MCMs)

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. ***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.

In order 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 Requirement:
n/a

Desired Education:
Our ideal candidate will possess a juris doctorate degree from an accredited institution of higher learning.

Desired Professional Experience:
Our ideal candidate will possess:

- Experience applying the Food, Drug and Cosmetic (FD&C) Act or similarly complex federal statute in regulatory or compliance activities.
- Experience applying laws and policies to prepare for or respond to public health emergencies.
- Experience communicating regulatory, legal and policy issues to stakeholders.
- Ability to analyze, evaluate, and interpret complex Federal statutes and regulations, legal and regulatory guidelines and agency policies to advise on program operations, develop policy, or provide guidance and consultation.
- Ability to meet and deal effectively on behalf of the FDA, or similarly complex regulatory agency, with internal and external stakeholders and effectively represent equities in internal and external engagements.
- Demonstrates skills in written and verbal communications in the preparation and presentation of written documents and briefings.

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: Non-Sensitive/Low Risk

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 the requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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

All qualified candidates should submit their resume with cover letter and unofficial transcripts (if you have foreign transcripts, please submit foreign transcript evaluation from an accredited company) by February 24, 2023 to: Karen.Drinnon@fda.hhs.gov

How You Will Be Evaluated

Candidates may be evaluated based on an interview, review of requested work samples, writing samples, most recent performance evaluation(s), professional references, results of an oral presentation or work-related test. Failure to comply with any of the ~~a~~ssessment requests will result in removal from further consideration. [Good but perhaps edit as highlighted in green]

Announcement Contact

For questions regarding this Cures position, please contact: Karen.Drinnon@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.