Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Management (OM)
Division of User Fee Management (DUFM)

Application Period: April 2, 2024 – April 16, 2024

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): Silver Spring, MD

Salary: Starting at $117,962 - $185,346

Work Schedule: Full-Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

Bargaining Unit: 3591

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 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 Center for Drug Evaluation and Research (CDER) is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.

The mission of the Office of Management (OM) to provide trusted, timely management information and services with our diverse, empowered workforce of professionals who enable the Center for Drug Evaluation and Research to achieve its public health goals and objectives.

The Division of User Fee Management (DUFM) obtains the resources necessary for the Center and Agency to achieve their mission of promoting and protecting public health. DUFM does this by providing central oversight and management of CDER's user fee programs, including the Prescription Drug User Fee Amendments (PDUFA), the Biosimilar User Fee Amendments (BsUFA), the Generic Drug User Fee Amendments (GDUFA), the Compounding Quality Act (CQA), and the Over-the-Counter Monograph User Fee Program (referred to as OMUFA).

Duties/Responsibilities

As a **Regulatory Counsel,** the incumbent is responsible for ensuring that regulations and policies developed in an assigned area are consistent with statutory requirements and existing policy. The incumbent handles complex assignments of national scope and significance. The work performed by the Regulatory Counsel in the Policy and Operations (POB) includes preparing responses to citizen petitions and/or petitions for reconsideration; drafting and commenting on legislation; and providing advice on the interpretations of the laws, regulations, and policies applicable to the FDA. The employee is recognized for their user fee experience within the development of medical policy, procedures, and policy initiatives pertaining to human drug development, human drug approval, bioresearch monitoring, and human subject protection, which is legally complex and may involve scientifically difficult and politically sensitive issues.

- Prepares responses to citizen petitions and/or petitions for reconsideration; drafts and comments on legislation; and provides advice on the interpretations of the laws, regulations, and policies applicable to FDA.
- Serves as a regulatory resource regarding the statutes, regulations, policies, procedures, and implications relevant to the issuance of FDA regulations and petition responses, conducts sophisticated analyses of complex regulatory and policy issues, and provides advice to staff in CDER in carrying out its regulatory mission.
- Works with complex and difficult assignments of national scope and significance. The incumbent assumes responsibility for ensuring that regulations and policies developed in the assigned areas are consistent with the statutory requirements and existing policy, that their need is justified, and that they are adequately supported by appropriate analysis including adequate scientific and medical analyses when required.
- Performs duties that include user fee-related issues concerning the application of any of FDA's enabling statutes, pertinent user fee regulations, and/or general laws affecting the operation of POB. Assignments are often complicated by the need to research complex or controversial regulatory and policy issues of wide public interest.
- Drafts documents for review that embody policy and program proposals on user fee products including regulations, citizen petition responses, proposed legislation, and

policy statements. These regulations and policy statements often result from the need to implement new legislation or from new interpretations of existing laws. They may be broad in scope and affect either an entire or a significant sector of a regulated industry.
- Works with groups of scientific, regulatory, and legal experts to develop new or revised regulations and drafts the resulting notices of proposed rulemaking.
- Reviews and prepares draft responses to public comments received on proposed user fee regulations and recommends adoption or rejection of counter-proposals contained in comments and objections.
- Drafts replies to correspondence from the regulated community, Congress, and other interested persons on user fee issues that concern precedent-setting interpretations of laws governing FDA and FDA's user fee policy.
- Consults with appropriate scientific experts and drafts responses to citizen petitions and/or petitions for reconsideration. Participates in working groups to resolve difficult and controversial issues raised by citizen petitions and/or petitions for reconsideration.
- Drafts comments on proposed legislation on matters pertaining to FDA's user fee jurisdiction.
- Advises DUFM and OM on new user fee regulations and advises the POB Branch Chief on the sufficiency and procedural adequacy of proposed policy statements and policy initiatives.
- Provides guidance and/or training to subject matter experts within DUFM on user fee matters.
- Advises staff in the Division and OM and, under the direction of Senior Regulatory Counsels, engage in discussions with OCC and other Offices across CDER on matters related to the Regulatory Counsel's user fee responsibilities.
- Drafts regulations, petition responses, and other written statements of Agency user fee policy. The Regulatory Counsel consults with staff within the Division and Office to identify areas of disagreement within the Center or between the Center and other units of FDA, to resolve disagreements through the use of decision memoranda or through meetings, and to articulate any policy consensus reached through this process.
- Uses resources such as Westlaw, LexisNexis, MediRegs, the U.S. Code, the Code of Federal Regulations, the Federal Register, and others, to conduct research regarding established precedents in order to draft and support legally sufficient regulations, citizen petition responses, and policies.

Supervisory Responsibilities: N/A

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.

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:

Regulatory Counsel, AD-0301 Series:

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.

Desired Professional Experience:
Our ideal candidate will possess:

- A minimum of 5 years' experience supporting the development, review, or new interpretations of existing legislation related to user fees.
- Possession of significant knowledge of regulatory practice, policies, and procedures, with experience related to the regulation of user fees is desired.
- Mastery in their ability to communicate orally and in writing and work with staff at all levels of the organization and varying levels of domain expertise.
- Knowledge of health science applicable to policy development across a wide range of technical and clinical subject matter, and skill in applying this knowledge in solving complex policy problems involving diverse aspects of regulatory science.
- Mastery skill in developing policies involving priority matters affecting the regulation of drug products.
- Mastery of knowledge of pertinent regulatory information in Agency manuals, reference systems, directives, issuances, precedent decisions, court decisions, and commercial publications or similar background information.

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 Recognition of Foreign Qualifications | International Affairs Office (ed.gov)

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/High 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.

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

Submit resume or curriculum vitae with cover letter by **April 16, 2024,** to: Roland Reynolds at roland.reynolds@fda.hhs.gov. Candidate resumes may be shared with hiring official within the CDER/OM with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share."

Announcement Contact

For questions regarding this Cures position, please contact: CDER-OM-IO-AdminTeam@fda.hhs.gov.

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FDA is an equal opportunity employer.