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)
Policy and Operations Branch (POB)

Application Period: May 7, 2024 – May 17, 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: Lead Regulatory Counsel

Series: AD-0301

Location(s): Silver Spring, MD

Salary: $132,368 - $203,349

Work Schedule: Full-Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

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) 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) is 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).

The Policy and Operations Branch (POB) supports DUFM by analyzing relevant statutory and regulatory provisions, drafting memoranda, correspondence, and other regulatory documents to communicate decisions related to PDUFA, BsUFA, GDUFA, OMUFA, and CQA user fee programs.

Duties/Responsibilities

As a **Lead Regulatory Counsel**, within the Policy and Operations Branch (POB), Division of User Fee Management (DUFM), Office of Management (OM) the incumbent assumes primary responsibility for ensuring that regulations and policies developed in the assigned area are consistent with statutory requirements and existing policies.

- Provides a justified need, and that scientific and regulatory decisions have been appropriately documented.
- Handles the most highly complex and difficult assignments of national and international scope and significance.
- Provides regulatory support to DUFM senior leadership and DUFM-led project working groups in the development and revision of policies, programs, regulations, and guidance involving the most complex and highest priority matters affecting user fees.
- Drafts or critically reviews documents embodying policy and program proposals and decisions. These documents state or interpret CDER or FDA policy for the regulated industry and other affected groups and receive minimal review before transmittal to Center management.
- Reviews policy and other regulatory documents drafted by other CDER Offices, such as Office of New Drugs (OND), Office of Generic Drugs (OGD), Office of Surveillance and Epidemiology (OSE), and Office of Compliance (OC), that impact user fee obligations and regulation. Evaluates other Office policies (regulations, guidance, and programs), both final and draft, as to impact on user fee obligation and regulation and provides recommendations to harmonize.

- Serves as an expert consultant in regulatory matters related to user fee assessment and is frequently called on to advise others, including OM staff and management, concerning FDA statutes and regulations related to user fees.
- Represents DUFM senior management in discussions of policy/regulatory matters involving other OM offices or CDER super-offices.
- Drafts or reviews proposals for new regulations and policy statements concerning CDER-led user fee programs. 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 generally affect either an entire industry or a significant sector of the regulated industry.
- Performs policy/regulatory reviews of the most complex or controversial user fee-related issues and critically assesses policy/regulatory reviews performed by other DUFM staff, including regulatory counsels.
- Provides technical oversight of the development of one or more courses of action and the drafting of consult responses to these work products.
- Represents the Division, consistent with the goals and objectives of DUFM management, in certain discussions with the Office of Chief Counsel concerning user fee assessment, refunds, waivers, or other similar issues raised by industry, including discussions concerning consistency in application of user fee actions within the Center and across other various Centers with regard to CDER-led user fee programs.
- Advises DUFM staff on how to comply with procedures and methods involved in implementing new programs, guidance, and regulations, and in revising existing programs, guidance's, and regulations, and on the regulatory sufficiency and procedural adequacy of proposed policy statements and policy initiatives.
- Prepares and replies to correspondence from the regulated industry, members of Congress, and other interested persons on policy/regulatory issues related to user fees that are industry-wide in scope or have broad policy implications and that concern precedent-setting interpretations of FDA policy concerning user fees.
- Coaches the team in the selection and application of appropriate problem-solving methods and techniques, provides advice on work methods, practices, and procedures, and assists the team and/or individual members in identifying the parameters of a viable solution.
- Leads the team in identifying, distributing, and balancing workload and tasks among employees in accordance with established workflow, skill level and/or occupational specialization; adjusting the workload in accordance with established priorities to ensure timely accomplishment of assigned team tasks; and ensuring that each employee has an integral role in developing the final team product.

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 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:

Regulatory Counsel, AD-0301 Series:
A law degree, specifically a LL.M. or J.D. The degree must be from an accredited program or institution.

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.
- 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/Moderate 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 qualifications 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; Letter of interest (no longer than 1 page) indicating why you are interested in being considered for this detail.; Copy of most recent SF-50 (Notification of Personnel Action) identifying current pay plan, series, grade; by **May 17, 2024** to: Roland Reynolds at Roland.Reynolds@fda.hhs.gov. Candidate resumes may be shared with hiring officials within CDER/OM with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share".

How I 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 additional assessment requirements will result in removal from further consideration.

Announcement Contact

For questions regarding this Cures position, please contact Roland Reynolds at Roland.Reynolds@fda.hhs.gov.

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

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