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: July 1, 2024 – July 15, 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: Policy & Operations Branch Chief, Division of User Fee Management

Series: AD-0343

Location(s): Silver Spring, MD

Salary: $139,395 - $191,900

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 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) provides legal and analytical support to the Division of User Fee Management by interpreting relevant statutory and regulatory provisions. The POB advises the Director and staff on the scope and meaning of regulatory and statutory requirements, drafts decision memoranda and correspondence to support and communicates decisions, and reviews evidence for legal and administrative actions. The mission is to ensure the Division's conformity with applicable law and to effectively document and communicate decisions and interpretations to the industry.

Duties/Responsibilities

As the **Policy & Operations Branch Chief** within the Division of User Fee Management, the incumbent is responsible for directing and overseeing staff engaged in conducting management studies, analyses, and evaluations to enhance the effectiveness and efficiency of user fee collections program operations. This involves identifying and resolving complex regulatory, financial, and policy-related issues affecting the user fee collections process, as well as ensuring daily transactions and collections activities are carried out in compliance with OMUFA and CQA requirements. The successful execution of these duties requires a deep understanding of user fee program operations, financial management principles, relevant regulatory frameworks, and the ability to analyze complex issues and develop effective solutions to improve program performance.

- 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.
- 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.

- 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.
- Manages Policy and Operations Staff resources to maximize the effective and efficient use of funds and employee skills. Reviews operational costs, operating schedules, and performance. Develops budgets and staffing plans that accurately account for current and anticipated strategic and operational requirements.
- Provides administrative and technical supervision to the Policy and Operations Branch. Models' leadership qualities to subordinate staff, mentors' staff, and provides training and/or hands-on learning experiences to enhance staff's knowledge, skills, and abilities. Establishes guidelines and performance expectations that are communicated clearly to staff members through the formal employee performance management system; observes workers performance; and conducts work performance reviews. Provides feedback and periodically evaluates employee performance; resolves conflicts and grievances; develops work improvement plans; and recommends personnel actions. Provides advice and counsel to staff related to work and administrative matters; effects disciplinary measures as appropriate; and reviews and approves or disproves leave requests.

Supervisory Responsibilities: The incumbent has direct supervisory responsibility over approximately 20 employees, including management analysts, program coordinators, and other regulatory and administrative staff within the branch. The incumbent spends approximately 35% of their time providing occupational-specific technical and administrative supervision to subordinates performing critical policy analysis, program planning, user fee billing and collections, regulatory compliance, and related activities supporting FDA's user fee programs.

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:
Management and Program Analysis, AD-0343 Series:
There are no Individual Occupational Requirements for this series.

For more information, please see: **OPM Occupational Series Qualification Requirements**.

Desired Education: Our ideal candidate will possess a graduate degree in law, public policy, public administration, business administration, or a related field relevant to overseeing regulatory policy and user fee program operations and/or a Juris Doctor, preferred but not required.

Professional Experience: Our ideal candidate will possess a minimum of 5 years of operations management experience in User Fee Management or related field.

Desired Professional Experience:
Our ideal candidate will possess:

- Extensive knowledge of FDA's policies, procedures, and practices related to user fee billing, collections, fee setting, and program reauthorization negotiations.
- Excellent oral and written communication abilities to advise senior leadership, draft decision memoranda and policy documents, and represent the organization on regulatory matters.

- Proficiency in identifying training needs, mentoring staff, and providing developmental opportunities to enhance team capabilities.
- Strong strategic planning, program management, and project oversight skills, including experience developing and implementing long-term and operational plans.

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 **July 15, 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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free environment.

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