



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 (DUFM)

Application Period: June 28, 2023 – July 10, 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: Deputy Division Director, Division of User Fee Management **Series:** AD-0343

Location(s): Silver Spring, MD **Salary:** \$163,964- \$225,011

Work Schedule: Full Time

Cures Band(s): Band E **Full Performance Band Level:** Band E

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).

Duties/Responsibilities

As the **Deputy Director for the Division of User Fee Management (DUFM)**, the incumbent assists the Director in providing leadership and oversight to the Immediate Office and 3 Branches. In this capacity, the incumbent supports the Director in meeting Division goals, securing and managing the resources necessary for Center for Drug Evaluation and Research (CDER) to execute its public health mission. through effective user fee program operations, reauthorization negotiations, budget planning, and financial management. The Deputy Director has direct oversight of the Immediate Office and serves as the alter ego for the Director in providing leadership and oversight to employees involved in managing collection of fee assessment activities for user fee programs (PDUFA, GDUFA, BsUFA, OMUFA and Compounding Quality Act) totaling \$1.6 billion.

- Ensures that staff are hired, trained, supported, and evaluated properly to maximize the success of the Division. The Deputy Director interacts with a wide range of Offices throughout CDER, the Agency, and with portions of regulated industry to implement and execute the relevant user fee programs.
- Monitors incoming payments from regulated industry to ensure compliance with user fee statutes.
- Works with industry to address questions about user fee obligations.
- Prepares, supports, and participates in reauthorization negotiations.
- Provides input to determine annual user fees in PDUFA, GDUFA, BsUFA, CQA, and OMUFA.

Supervisory Responsibilities: Works with the Division Director leads a division comprised of 3 branches: Generics Branch, the Policy & Operations Branch, and the Brands Branch. Provides occupational specific technical and administrative direction and supervision 25 percent or more

of the time to subordinate staff performing the work and functions of the organizational unit. Obtains resources, identifies strategic objectives, and establishes goals for the Division. Executes strategic objectives for the organization.

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 Master of Business Administration Degree and/or a Juris Doctor, preferred but not required.

Desired 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:

- Ability to align and link administrative strategic plans and objectives to mission's strategic plans.
- Knowledge and understanding of current FDA regulations, policies, and procedures.
- Ability to manage cross-functional teams, unite and engage staff for performance management; communicate and work toward organizational goals, and develop process improvements.

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

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 10th, 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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