



Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Management (OM)

Application Period: March 6, 2023 – March 31, 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: Division Director, Division of User Fee Management

Series: AD-0301

Location(s): Silver Spring, MD

Salary: \$177,123- \$254,461

Work Schedule: Full Time

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: 25% or less

Bargaining Unit: 8888 (Non-Bargaining)

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 **Director for the Division of User Fee Management (DUFM)**, the incumbent operates as a senior level manager providing leadership, oversight, and execution of responsibilities to obtain the resources necessary for the Center and Agency to achieve their mission of promoting and protecting public health. The incumbent provides central oversight and management of CDER's user fee programs, including the Prescription Drug User Fee Act (PDUFA), the Generic Drug User Fee Amendments (GDUFA), Biosimilar User Fee Act (BsUFA), the Compounding Quality Act (CQA), and the Over-the-Counter Monograph Drug User Fee Program (OMUFA). The Director coordinates and manages the financial and resource management and operational planning for user fee programs totaling \$1.8 billion.

Manages the collection and fee assessment activities for user fee programs and the collaboration with a wide range of Offices throughout CDER, the Agency, and portions of regulated industry to implement and execute operational aspects and high-level decisions of user fee programs used in CDER. The Director provides leadership and direction to subordinate Branch Chiefs and other staff responsible for the following activities:

- Monitoring incoming payments from regulated industry to ensure compliance with user fee statutes.
- Working with industry to address questions about user fee obligations.
- Preparing for, supporting, and participating in reauthorization negotiations.
- Providing input to determine annual user fees in PDUFA, GDUFA, BsUFA, CQA, and OMUFA.

Serves as an advisor to the Office of Management (OM) Director and Deputy Director providing authoritative guidance and recommendations on analyzing and determining budget trends and funding levels for Center's user fee programs and activities. Oversees the establishment of

program strategic goals, structure, and processes necessary to implement the organization's mission and vision of the user fee programs and operational needs of the Center. Manages the assessment of program feasibility by formulating short-and long-term goals; structuring and organizing work; setting priorities; anticipating, identifying, diagnosing, and consulting on potential problems areas; establishing management standards; and utilizing procedures and processes to monitor progress toward organization objectives.

Supervisory Responsibilities: Leads and directs a Division comprised of 65 full time equivalents that includes subordinate supervisors and skilled technical staff. Ensures that staff are hired, trained, supported, and evaluated properly to maximize the success of the Division. Defines jobs, selects employees, and assigns work; defines technical work requirements and milestones; evaluates the organization and employee accomplishments by accepting or rejecting work products; and presents and defends the organization's work to senior management and other offices. Recommends employee promotions and recognition; approves leave; implements performance modifications; and takes corrective actions as appropriate.

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: N/A

Miscellaneous Administration and Program Series, AD-0301

There are no Individual Occupational Requirements for this series.

Desired Education: Our ideal candidate will possess a Master of Business Administration Degree and/or a Juris Doctor.

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:

- Demonstrated ability to strategically manage human, information, and budget planning resources.
- Possess knowledge and experience in government programs, contract management, reporting, applying Federal rules and regulations applicable to managing in an operational environment.
- 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 [U.S. Department of](#)

[Education website for Foreign Education Evaluation.](#)

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.

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

How to Apply: Submit resume or curriculum vitae with cover letter by **March 31, 2023** 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.” For questions, please contact Roland Reynolds at Roland.Reynolds@fda.hhs.gov.

Announcement Contact

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

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

FDA is an equal opportunity employer.

