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)
Brands Branch (BB)

Application Period: July 17, 2024 – July 30, 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: Pharmacist

Series: AD-660

Location(s): Silver Spring, MD

Salary: $117,962 - $164,260

Work Schedule: Full-Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: Up to 25%

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) is to provide trusted, timely management information and services with our diverse, empowered workforce of professionals who enable CDER 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 Brands Branch (BB) within DUFM plays a critical role in managing and implementing the administrative and business processes for the PDUFA and BsUFA programs. Its key responsibilities include issuing annual bills for program fees, advising on applicable fees for new drug applications, and addressing industry requests for waivers, exemptions, and refunds. It is pivotal in ensuring the compliant execution and smooth operation of the PDUFA and BsUFA user fee programs.

Duties/Responsibilities

As a **Pharmacist** within DUFM, the incumbent supports the operational development, implementation, and oversight of user fee programs mandated by PDUFA and BsUFA. The incumbent will apply scientific expertise in pharmacy and regulatory knowledge to ensure compliant execution of these vital user fee programs that provide resources for CDER's drug review activities.

- Applies scientific knowledge in areas of clinical pharmacy and pharmacology to monitor incoming submissions of human drug applications and supplements for New Drug Applications (NDAs) and Biologics License Applications (BLAs) to the Agency, ensuring appropriate user fees are assessed in accordance with the Food, Drug, & Cosmetic Act (FD&C) for each submission.
- Evaluates request for waivers, exemptions, and refunds as per the FD&C Act. Conducts independent research, prepares comprehensive reports and presentations based on gathered data from diverse sources, and makes recommendations and detailed findings from analyzed regulatory and scientific information.
- Manages user fee data, responds to industry inquiries, and generates reports and statistics to track user fee revenues and support program reauthorization processes.
- Reviews recommendations for regulatory actions related to User Fees within the Office and Center. Provides technical expertise and leadership in the development and implementation of new user fee programs as authorized by Congress. Analyzes legislation to identify key provisions and implications for CDER. Develops comprehensive plans and timelines for operationalizing new programs. Coordinates across CDER offices to ensure successful launch and ongoing administration of new user

fee programs. Serves as project lead and participates in Center-wide user fee program working groups.

- Develops regulations, guidance documents, correspondence, and other written statements of Agency policy concerning user fees. Applies expertise in pharmacy and regulatory science to draft clear, scientifically sound, and legally compliant documents. Collaborates with legal, policy, and program experts to ensure accuracy and consistency with Agency objectives.
- Supports the implementation of statutory updates related to the PDUFA and BsUFA user fee programs. Reviews new legislation to identify provisions impacting user fees. Works with team to interpret new requirements, update processes and procedures, and communicate changes to relevant stakeholders. Contributes to development of guidance, SOPs, and other materials to operationalize statutory provisions.

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.

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:

Pharmacy, AD-0660 Series:

Degree: Doctoral degree in Pharmacy that is recognized by the Accreditation Council for Pharmacy Education (ACPE), or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Licensure Requirements:

Applicants must be licensed to practice pharmacy in a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

For the Band C and above: In addition to the licensure and educational requirements described above, a minimum of one (1) year of professional pharmacy experience that is equivalent to at least the next lower Band level.

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

Desired Skills, Experience, or Education:
Our ideal candidate will possess:

- Experience applying scientific knowledge in areas of clinical pharmacy and pharmacology to monitor drug submissions and ensure regulatory compliance for user fee assessments.
- Experience conducting regulatory evaluations, including waivers and exemptions, with advanced skills in research, data analysis, and report creation.
- Experience managing user fee programs, coordinating projects, and providing expert guidance on FDA regulations and policy development.
- Knowledge of the Food, Drug, and Cosmetic Act and ability to apply broad knowledge of US drug law and regulatory policy.
- Skill in oral and written communication to make presentations, participate in meetings, draft public communications and reports.

- Ability to make timely decisions under ambiguous circumstances to keep projects on schedule.
- Experience discussing controversial issues with multiple stakeholders and negotiating with regulated industry to gain acceptance of recommendations and requirements.

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 30, 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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