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 Generic Drugs (OGD)
Office of Generic Drug Policy (OGDP)
Division of Legal and Regulatory Support (DLRS)
Division of Orange Book and Regulatory Assessment (DOBPRA)

Application Period: December 20, 2023 - January 4, 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-0660

Location(s): Silver Spring, MD

Salary: Starting at $112,015

Work Schedule: Full-Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

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 (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The mission of the Office of Generic Drugs (OGD) and its sub offices is to ensure high-quality, affordable generic drugs are available to the American public. OGD is the world leader in the science and regulation of generic drugs serving an essential role in advancing FDA's public health mission.

The Office of Generic Drug Policy (OGDP) serves as the Agency lead on generic drug policy and regulation to enable generic drug approvals and provide the public with high quality, affordable medicines. We achieve this by advocating on behalf of the generic drug program and providing counsel in a complex, ever-changing legal and regulatory environment.

The Division of Legal and Regulatory Support (DLRS) mission is to advise the Office of Generic Drugs on generic drug application specific legal regulatory and policy issues in the course of FDA implementation of Section 505(j) of the Federal Food, Drug, and Cosmetic (FD&C) Act. The Division is responsible for providing expertise on generic drug regulatory issues at both the Center and Agency level.

The Division of Orange Book Publication and Regulatory Assessment (DOBPRA) publishes and maintains FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book," and makes recommendations on and coordinates the resolution of policy issues related to the patent and exclusivity, substitutability, and drug product information that appears in the Orange Book, and also supports the development of policy deliverables related to the Orange Book.

Duties/Responsibilities

As a **Pharmacist**, the incumbent provides technical direction to various aspects of the assessment of ANDAs and other generic drug submissions. The pharmacist performs regulatory duties that support the public health mission to help ensure high quality, affordable generic drugs are available to the American public.

- Ensures the availability of therapeutically-equivalent generic drug products to the American public through coordination with senior-level scientists and subject matter experts, such as regulatory counsels and clinicians, to conduct regulatory science research, evaluate generic drug applications, and/or investigate and research potential post-approval safety or product use issues.

- Serves as a scientific and technical expert providing assessment and evaluation for the generic drug process and program activities within OGD. Carries out activities to determine the acceptability of Abbreviated New Drug Applications (ANDAs) such as data evaluation as part of the review process for applications, submitted under section 505 (j) of the Federal Food, Drug and Cosmetic (FD&C) Act.
- Compiles data to prepare periodic and special reports relative to the work of the division for issuance to generic drug applicants and presentations or manuscripts for public venues or guidance.
- Replies to correspondence from regulated industry and stakeholders to provide counsel as needed. Issues raised in these correspondences are often both regulatory and technical in scope. Leverages available methods, technology, and information to produce a quality work product. Prepares written deliverables in collaboration with team embers that convey relevant product development information to the generic drug industry.
- Provides input, recommendations, and innovative strategies when collaborating with experts within the Office to modify and develop systems, policies, and procedures to address the needs of the program segments.
- DLRS: Assesses patent and exclusivity matters for brand and generic drugs and determine timing of generic drug approval. Manages programs for adjudicating eligibility for priority review of applications, coordinating OGD's response to drug shortages, and compiling and reporting on certain information related to generic drugs, including statutorily required reports to Congress.
- DOBPRA: Operates and maintains the Orange Book publication as a Subject Matter Expert (SME), which includes but is not limited to the assessment of new and abbreviated new drug application-specific submission data for drug product listings and certain marketing protections.

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.

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.

Medical Requirements:
Applicants must be able to distinguish basic colors.

Qualifying Experience:
For the Band C and above, in addition to the licensure and educational requirements described above, applicants must have:

- Three (3) years of progressively higher-level graduate education leading to a Ph.D. degree, Ph.D., Pharm.D. or equivalent doctoral degree.

- A minimum of one (1) year of professional pharmacy experience that is equivalent to at least the next lower Band level.
- Dispensing medications prescribed by physicians and other health practitioners and providing information to health practitioners and patients about proper usage of medications and side effects.
- Evaluating medication use patterns and outcomes for patients in hospitals or managed care organizations.
- Performing administrative, consultative, or staff advisory work for a medical facility's pharmacy program.
- Planning, monitoring, and evaluating medication programs or regimens.
- Establishing medication-handling procedures for the storage and preservation of medications.
- Researching medical literature and/or clinical medication information to provide accurate responses to inquiries; and/or
- Maintaining all medication records required by law.

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

Desired Professional Experience:
Our ideal candidate will possess:

- Experience identifying and analyzing problems; weighing relevance and accuracy of information; generating and evaluating alternative solutions; and make recommendations and/or implement program changes.
- Experience assessing information/data and make decisions on complex issues related to drug products.
- Skills in verbal communications to present findings and conduct briefings.
- Ability to communicate in writing in order to prepare deliverables (e.g., to prepare written documents and findings) that convey relevant product development information to the generic drug industry.

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.

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 as a single document file by **January 4, 2024,** to: OGDPPMASTeam@fda.hhs.gov. Candidate resumes may be shared with hiring official within CDER 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 OGDPPMASTeam@fda.hhs.gov.

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

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