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 Regulatory Policy (ORP)

Application Period: March 7, 2023 – March 26, 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: Pharmacist

Series: AD-0660

Location(s): Silver Spring, MD

Salary:
Starting at $132,368

Work Schedule: Full-Time

Cures Band(s): Band D

Full Performance Band Level: Band D

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 and prescription drugs, including biological therapeutics and generic drugs.

The mission of the Office of Regulatory Policy (ORP) is to provide Center oversight and leadership in the development of regulations, policies, procedures, and guidance's that affect the drug approval process, and in the development of new legislation. Also, ORP manages the disclosure of official records and information under the Freedom of Information Act, Privacy Act, other statutes, and Food and Drug Administration's public disclosure regulations.

Duties/Responsibilities

As a **Pharmacist,** within the Immediate Office, Office of Regulatory (ORP), the incumbent provides leadership and scientific knowledge to the areas of pharmacy practice and regulatory issues as they relate to the Food, Drug, and Cosmetic Act, the Public Health Service Act, the Paperwork Reduction Act, the Drug Price Competition and Patent Term Restoration Act, the
Generic Animal Drug and Patent Term Restoration Act, and the Leahy-Smith America Invents Act Serving as a scientific member of a multidisciplinary team of professionals, the incumbent is responsible for reviewing a wide range of related issues within the Office and across the Center, and for participating in a range of functions related to implementing patent term restoration provisions. Duties include, but are not limited to:

- Serves as a senior pharmacist, and as a recognized expert in patent term extensions, incumbent provides information, advice, and consultation to hospitals, pharmaceutical industry, federal agencies such as FDA, and U.S. Patent and Trademark Office (USPTO) and/or universities on unique and complex regulatory issues involving patents and regulatory review period determinations.
- Serves as an expert in legislation, policies, procedures, the incumbent plans for and provides technical pharmaceutical advice and guidance to others in the areas of expertise. Performs review of the application when it is necessary to determine whether the product is eligible for patent term restoration, what took place during the review of the product, and whether challenges of the eligibility of a certain product or the regulatory review period determinations are adequately addressed.
- Notifies the USPTO when adequate term for comment and review is completed. Serves as an official liaison and collaborates on a national level with scientists and government officials on a wide range of regulatory issues. Provides specialized expertise in evaluating chemistry as well as specialized analytical expertise in consulting on a wide variety of pharmacy related regulatory issues and matters.
- Reviews a wide range of related issues across the Agency related to implementing the patent term restoration provisions of the Drug Price Competition and Patent Term Restoration Act, the Generic Animal Drug and Patent Term Restoration Act, and the Leahy-Smith America Invents Act. These issues and duties include determining the term of regulatory review by which a patent term may be extended, and the Agency works with the US Patent and Trademark Office to determine how much time elapsed during the drug review process so that an innovator's patent can be extended. The incumbent will be expected to assist in understanding how long the review process was and the degree to which complicated scientific issues extended the review time.
    - Evaluates Patent Term Extension (PTE) Applications and USPTO consult requests to determine whether the PTE application is eligible for patent term extension. This requires comparison and evaluation of prior approvals of drug, biologic, device, animal drug and food products with the product currently under consideration and requires substantial understanding of product chemistry and manufacturing processes. It also requires the incumbent to interact with the Centers review divisions to determine whether a submission is for a new product or one that was previously approved in some other form. Gathers the

supporting documentation required to determine the regulatory review period of the product for the USPTO and determining the regulatory review period for the application and the time available for extension. It also requires an understanding of the review process and the degree to which complicated scientific issues extended the review time. Publishes notice of the regulatory review period for the application in the Federal Register.

- Responds to citizen's petitions challenging the findings included in the regulatory review period or the due diligence of the applicant. Provides follow up responses to the USPTO consults and Center's review divisions as required. Maintains statistics of PTE applications completed and status.
- Performs project management for projects sent to Regulations Editorial Staff for publication and responds to challenges of the regulatory review periods as published or the due diligence of the patent term applicant.
- Serves as a recognized expert in matters related to his or her area of responsibility and is frequently called on to advise others concerning requirements of the Paperwork Reduction Act of 1995 (PRA) as it relates to collection of information under FDA statutes, regulations, and guidance. Assists in determining whether these collections of information are necessary, as well as estimating the burden of these collections of information and other PRA implications of program requirements or program guidance The PRA is a law passed to monitor the amount of information that the Federal government collects from the public, and regulated industries, ensuring that federal agencies do not overburden the public with federally sponsored data collections. The PRA ensures that the information collections federal agencies undertake, or sponsor are necessary and serve a useful purpose. Compliance with the PRA is essential because legal collection of vital information to fulfill the Agency's mission can only be accomplished with the Office of Management and Budget (OMB) approval. Examples of FDA sponsored information collections include the data submissions required to support the drug approval process and related postmarked submissions, registration and listing of companies manufacturing or distributing FDA regulated products, and certain drug labeling.

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 is required.
- Financial Disclosure is required.
- Ethics Clearance is required.

- Background Investigation/Security Clearance is required.

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 Series, AD-0660

Degree: A 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. For more information, see: OPM Occupational Series Qualification Requirements.

Desired Skills, Experience, or Education:

Our ideal candidate will possess:

- Demonstrated knowledge of pharmacy science and therapeutic biologics is highly desired.
- Demonstrated knowledge of current pharmacy practice, the clinical application of drugs, the therapeutic use of drugs is highly desired.
- Demonstrated experience and ability to identify and analyze problems; weighing the relevance and accuracy of information; generating and evaluating alternative solutions; and making recommendations.
- Demonstrated experience and knowledge in regulatory practices, policies, and procedures.
- Demonstrated ability utilize project management skills to organize time effectively, determine priorities, and meet established deadlines.
- Demonstrated knowledge and ability to work independently and as a contributing, collaborative team member.
- Demonstrated ability to communicate orally and in writing
- Demonstrated experience and skill to collaborate across boundaries to build strategic relationships and to achieve common goals, including working with staff at all levels of the organization and varying levels of domain expertise.

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/Moderate Risk

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. Please refer to the Ethics Clearance Requirements section.

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 requires 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 **March 26, 2023**, to: CDER-ORP-Cures-Hiring@fda.hhs.gov. On the subject line, please reference "**Pharmacist Band D**. Candidate resumes may be shared with hiring officials within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions, please contact CDER-ORP-Cures-Hiring@fda.hhs.gov.

Job Reference ID: T-23-1010-D

How I Will Be Evaluated

Candidates may be evaluated based on an interview, review of requested work samples, writing samples, most recent performance evaluation(s), and professional references, results of an oral presentation or work-related test. Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Announcement Contact

For questions regarding this Cures position, please contact CDER-ORP-Cures-Hiring@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.