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 the Center Director(OCD)
Counter-Terrorism and Emergency Coordination Staff (CTECS)

Application Period: August 14, 2024- September 4, 2024

Area of Consideration: CDER Wide. Open to current employees. Must be currently employed by the Food & Drug Administration, serving on an appointment in the excepted or competitive service.

Position: Pharmacologist

Series: AD-0405

Location(s): Silver Spring, Maryland

Salary: $139,395

Work Schedule: Full Time

Full Performance Band Level: Band D

Cures Band(s): Band D

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.

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 and prescription drugs, including biological

therapeutics and generic drugs.

The Office of the Center Director (OCD) Immediate Office (IO) provides leadership and overall direction to all CDER activities to ensure that the mission of the Center is accomplished. CDER akes sure that safe and effective drugs are available to improve the health of consumers. CDER ensures that prescription and over-the-counter drugs, both brand name and generic, work correctly and that the health benefits outweigh known risks.

The Counter-Terrorism and Emergency Coordination Staff coordinate Center activities related to emergency situations involving CDER-regulated products or facilities. They provide consultation for consistent application of the Animal Rule to product development and provide consultation on the development and availability of safe, effective, and quality medical countermeasures (MCMs) for chemical, biological, radiological and nuclear (CBRN) threats and emerging infectious diseases.

Duties/Responsibilities

As a **Pharmacologist,** the incumbent serves as CDER's authoritative resource for the regulations commonly known as the Animal Rule (21 CFR 314.600-650 and 21 CFR 601.90-95) and leading expert on general and overarching issues related to product development under the Animal Rule.

- Identifies, analyzes, and/or addresses general and overarching issues related to the Animal Rule that are impediments to product development and regulatory review.

- Prepares authoritative, comprehensive analyses, and summaries of complex scientific and regulatory issues related to medical countermeasure development under the Animal Rule to support substantive recommendations and conclusions on guidance, policy, and regulation to senior management. Such issues may be of controversial nature and/or of significant congressional interest.

- Develops and contributes to FDA's Animal Rule-related guidances, policies, scientific and regulatory programs, and procedures to advance the development of medical countermeasures under the Animal Rule and to advance FDA's review of Animal Rule product applications submitted to CDER and Center for Biologics Evaluation and Research (CBER). In addition to their impact on FDA and regulated industry, such guidances, policies, programs, and procedures have a significant impact on other parts of the federal government engaged in medical countermeasure funding, development, and procurement, such as the Department of Defense, the Biomedical Advanced Research and Development Authority, and the National Institutes of Health.

- Develops and contributes to the implementation strategies for guidances, policies, programs, procedures, and legislation related to the Animal Rule and medical countermeasure development. In addition to their impact on FDA and regulated industry, such implementation strategies have a significant impact on other parts of the federal government engaged in medical countermeasure funding, development, and procurement, such as the Department of Defense, the Biomedical Advanced Research and Development Authority, and the National Institutes of Health.

- Develops and maintains electronic data standards, controlled terminology, and a technical specifications guide for animal efficacy studies and natural history studies submitted in Animal Rule product applications to support the collection of data in these studies, the electronic submission of the data in regulatory applications, and FDA's review of these critically important applications.

- Leads the intra-agency efforts to clarify for FDA, other federal agencies, regulated industry, scientific and academic establishments, and other stakeholders, FDA's implementation of legislation related to electronic data standards as applied to the unique circumstances of Animal Rule submissions and to develop necessary policies and strategies for implementing the Animal Rule data standards.

- Contributes to mandated and/or Agency-initiated reviews of FDA regulations and proposed rulemaking, and contributes to FDA's review and analysis of, and response to, comments submitted to FDA related to the Animal Rule or to issues that will have an impact on developing products under the Animal Rule.

- Participates as a subject matter expert in FDA commissioner briefings. Contributes to background documents to support FDA testimony for congressional hearings; information for Congress and congressional staff, such as Agency technical drafting assistance documents and answers questions submitted for the record; and FDA's review of proposed legislation on topics related to product development under the Animal Rule and medical countermeasure development.

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:

A bachelor's degree or higher in toxicology, pharmacology, pharmaceutics, environmental sciences, medicinal chemistry, pharmaceutical sciences, or related sciences. The degree must be from an accredited program or institution.

OR

American Board of Toxicology certification.

Specialized Experience:

- Demonstrated expert knowledge and understanding of drug and therapeutic biological product development.
- Demonstrated expert knowledge and understanding of nonclinical study review and issues related to the design, conduct,

- reporting, and interpretation of animal studies submitted in regulatory applications, including issues related to animal
- welfare and the need for ensuring data quality and integrity in regulatory studies.
- Demonstrated expert knowledge and understanding of relevant FDA regulations, guidance, policy, programs, and
- procedures, and medical countermeasure-related legislation
- Thorough knowledge of recent developments in the pharmacology discipline and associated scientific disciplines and the
- applicable Agency laws, regulations, policies, procedures and guidelines.
- Demonstrated ability to recognize the need for and then develop new approaches to solve critical or novel problems

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

If not previously completed, 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 these 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 **September 4, 2024**, to: CDER-OCD-OEP-Hires@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research (CDER) with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Announcement Contact

For questions, please contact CDER-OCD-OEP-Hires@fda.hhs.gov. Please reference Job ID: **Pharmacologist** in the email subject line.

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.