Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation & Research (CDER)
Office of New Drugs (OND)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM)
Division of Pharmacology Toxicology (DPT)

Application Period: April 24, 2023 – May 05, 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: Deputy Division Director

Series: AD-0401/0405/0415

Location(s): Silver Spring, MD

Salary: Starting at $155,700

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

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 are 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 Office of New Drugs (OND) is a dynamic, purpose-driven organization dedicated to the review of new drug applications (NDAs), interactions with the pharmaceutical industry and ultimately deciding whether the benefits of a drug outweigh the known risks. OND is a multi-disciplinary organization engaged in the oversight of human drug trials in the United States, in review of NDAs and biologics license applications (BLAs) for marketing drugs and therapeutic biologics in this country, and in regulating over-the-counter (OTC) drug products.

The Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM) oversees the development, review, and regulation of applications for drug and biologic products. The role of the Pharmacology and Toxicology division is to help assure the safety of new drugs. Pharmacology and Toxicology reviewers and supervisors are committed to maintaining the highest standards of science and to establishing uniform review practices across OND.

Duties/Responsibilities

As the **Deputy Division Director** of the Division of Pharmacology Toxicology for the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (DPT-ORPURM), the incumbent provides professional leadership and scientific direction to subordinate supervisors and division staff. Acts in the capacity of the Division Director in his/her absence and assists the Division Director with directing the review and evaluation of New Drug applications (NDAs) and Biologics License Applications (BLAs), amendments and supplements to determine if drugs are safe and effective.

- Leads the development of OND guidance that clarifies FDA's thinking on issues involving rare disease drug development.

- Serves as a professional participant in meetings/conferences and outreach programs with other clinical review divisions, Center and Agency officials, academia and regulated industry related to issues pertaining to safety, health hazards, contamination, recall actions, and other matters associated with the marketing of those drugs which fall within the purview of the Division.

- Participates fully in policy formulation and in planning and evaluating the programs and activities of the Office to ensure that the nonclinical discipline is represented and considered in all major Office decisions, and that actions are consistent with Office policies.

- Maintains current knowledge and understanding of the "state of the science", to include new and emerging nonclinical technologies, and OND policies to inculcate the most advanced nonclinical practice into the Office programs.

- Provides advice, counsel, or instructions to employees on scientific and clinical matters. Provides staff leadership and direction and advises the Office and Center directors in all matters related to the planning development, formulation, implementation, execution, administration, and coordination of activities which affect policies, programs, and goals involving the safety and effectiveness of drug products intended for human use.

Supervisory Responsibilities: Supervise and evaluate staff who serve as experts in their field, provide occupational specific technical and administrative direction and supervision to subordinate supervisors and staff.

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:

Deputy Division Director, AD-0401/0405/0415 Series

Competitive candidates will have earned a doctoral degree in one of the following:

General Natural Resources Management and Biological Sciences Series, AD-0401

Pharmacology Series, AD-0405

Toxicology Series, AD-0415

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

Professional Experience/Desirable Qualifications:
Our ideal candidate will possess:

- Excellent leadership skills, capable of providing supervision to the Rare Disease Program and providing guidance and input across OND and to other internal and external stakeholders.

- Excellent collaborative skills, capable of working with a wide range of individuals of all levels from both public and private organizations, including the Center, Office of the Commissioner, other FDA Centers, other Federal agencies, and Congress, as well as the scientific/medical community, academia, and industry, which requires tact, diplomacy and technical expertise in communicating Center/Agency policies.

- Excellent verbal and written communication skills in order to develop policy, guidance(s) to industry, internal procedures, Center-level responses to congressional inquiries, etc.

- Excellent skills in critical thinking and strategic vision, to advance OND's policies, research agenda, training, and collaboration across other divisions, offices and stakeholders.

- Solid understanding of the regulations and polices as well as experimental design, theories and practices utilized in new drug evaluation.

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 qualifications 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 accommodation to have an equal opportunity to apply for a job. An employee with a disability needs accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs 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 a resume or curriculum vitae with cover letter to: Marci.Ephraim@fda.hhs.gov

by May 05, 2023. 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

Please reference **Source Code: OND-DPT-1001** in the subject line of your submission.

Announcement Contact

For questions regarding this Cures position, please contact Marci.Ephraim@fda.hhs.gov.

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