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 New Drugs (OND)
Office of Immunology and Inflammation (OII)

Application Period: August 2, 2023 – August 15, 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: Office Director (Supervisory Physician)

Series: AD-0602

Location(s): Silver Spring, MD

Salary: Starting at: $235,000

Work Schedule: Full Time

Cures Band(s): Band G

Full Performance Band Level: Band G

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.

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 Office of New Drugs (OND) is a super office within the Center for Drug Evaluation and Research responsible for the assessment of new drugs and therapeutic biologics. OND provides clinical, nonclinical, and regulatory expertise on the full range of drugs and therapeutic biologics that can be made available to the American people.

The Office of Immunology and Inflammation (OII) reviews notices of claimed investigational exemptions for Investigational New Drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials. Evaluates for safety and effectiveness and approves New Drug Applications (NDAs) and Biologic Licensing Applications (BLAs) for products regulated by this Office of Neuroscience, specifically products related to anesthesia, analgesia, addiction, movement disorders, epilepsy, dementia, cognitive disorders, migraines, traumatic brain injuries, ear disorders, neuromuscular disorders, multiple sclerosis, stroke (vascular), and psychiatric diseases.

OII evaluates supplements that propose changes in the conditions upon which NDA/BLA approvals are based. Develops policy and procedures governing the review and evaluation of drug investigations and NDAs/BLAs. Also, evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs for products regulated by this Office of Neuroscience. Performs medical and scientific evaluations of submissions on generic drugs, drugs under monograph, and OTC drug products regulated by other offices in the Center, as applicable. Works collaboratively with the Office of Surveillance & Epidemiology to conduct continuing surveillance and medical evaluation of labeling, clinical experience, and reports submitted by IND sponsors, by NDAs applicants, and from other sources.

Duties/Responsibilities

As an **Office Director (Supervisory Physician),** the incumbent manages an immediate office and several divisions that perform scientific review and evaluation of drugs subject to regulation by CDER. As primary advisor to the Super Office Director in the Office of Immunology and Inflammation (OII). The incumbent is expected to establish scientific policy guidance; provide scientific and technical direction; evaluate research resources to support drug development; develop and direct Office programs; develop innovative strategies; provide leadership to subordinates and oversight of operations; and develop short/long term goals for the Office. This position provides executive level leadership in the management of multiple subordinate divisions within an OND Office that includes the following responsibilities:

- Directs through subordinate division directors, activities including evaluations for safety and efficacy and investigational new drug applications, supplemental new drug applications and amendments submitted by researchers and manufacturers.
- Renders advice to pharmaceutical firms on the appropriate methods for drug study to help assure patient safety, surveillance and medical evaluation of labeling, clinical experience, special reports, and other data submitted by manufacturers as required.

- Formulates and prepares information required for submission to advisory committees and special experts and consultants serving the Center and FDA; and makes decisions on approval or withdrawal of approval for new drug applications, investigational new drug requests, drug supplements, and marketed drugs throughout the U.S., as well as foreign drugs to be marketed in the U.S.
- Executes delegated authority for approval or non-approval of NDAs, BLAs, supplemental applications, for investigational new drug (INDs) requests, and for OTC drug and monograph products other than those delegated to the subordinate divisions. Such decisions can be of the most controversial, complex, or critical nature.
- Establishes and coordinates policy and program objectives of the office, subordinate review divisions, within the stated program objectives of the Office, Center, Agency, Department, and other government agencies. This includes making a variety of policy decisions that have a major impact on the pharmaceutical industry, academic drug researchers, patient communities, and private medical practitioners.
- Provides consultation and expert advice on the evaluation of drugs on behalf of the OND Senior Leadership, to other FDA Centers, other government agencies, foreign governments, and international organizations.
- Serves as scientific advisor and consultant to the Super Office Director and higher-level Agency officials on the functions and programs that are the responsibility of the office. The incumbent is expected to keep the Super Office Director, Deputy Super Office Director(s), and other Office Directors fully informed of programs, resources, and related considerations that would bear upon the planning, development, and administration of CDER's diverse programs as well as represent FDA at professional meetings, committees, and working groups, as well as prepare and present testimony to Congress as needed.

Supervisory Responsibilities: Manages a multi-disciplinary program, providing leadership and management oversight to subordinate division directors and support 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:

Medical Officer (Physician), AD-0602 Series:

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

Professional Experience:

Our ideal candidate will possess:

- Ability to drive collaboration, empower staff, provide expert advice and consultation, coordinate program activities, and spearhead important program initiatives.
- Knowledge of leadership principles and concepts regulating and evaluating new drugs and biological products.
- Ability to manage and lead a diverse interdisciplinary staff.

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 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 resume or curriculum vitae with cover letter by **August 15, 2023** to krista.yazdani@fda.hhs.gov. Candidate resumes may be shared with hiring officials within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference **Job Reference ID: OND-OII-3468** in the email subject line.

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), 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 Krista.yazdani@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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