Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of New Drugs (OND)
Multiple Vacancies

Application Period: September 27, 2021-October 22, 2021

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 Director for Safety

Series: AD-602/AD-601

Location(s): Silver Spring, Maryland

Salary: (AD-602) Starting at $195,000-$295,000/(AD-601) $144,128-$203,212

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

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 compensated 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 or Agency) 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 (OTC) 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, 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 new drug applications (NDAs) and biologics license applications (BLAs) for marketed drugs and therapeutic biologics in this country, and in regulating OTC drug products.

The incumbent serves as the Deputy Division Director for Safety (DDS) within one of the OND clinical review divisions listed below. The DDS provides professional leadership and scientific direction to subordinate staff involved in the review and coordination of postmarket safety activities.

Division of Neurology I
Division of Anti-Infectives
Division of General Endocrinology
Division of Rheumatology & Transplant Medicine
Division of Pediatrics and Maternal Health
Division of Rare Disease & Medical Genetics

Duties/Responsibilities

The incumbent serves as the DDS within an OND clinical review division. The DDS provides professional leadership and scientific direction to subordinate staff involved in the review and coordination of postmarket safety activities.

Serves as the technical and medical/clinical lead for the division in implementing CDER's Safety First initiative, facilitates and oversees interactions with the Office of Surveillance and Epidemiology (OSE), and works with the Division Director and staff to prioritize safety-related regulatory submissions (e.g., NDA/BLA Annual Reports, Periodic Safety Reports (PSR)).

Provides oversight, coordination, and technical medical/clinical expertise, and consultative services on the postmarket safety activities typically involving the broadest and most controversial, sensitive, and complex subjects that can have a potential impact on FDA programs and the public health.

Provides postmarket safety-related medical/clinical expertise and consultative assistance to Physician/Clinical Team Leader(s), Physicians, and Clinical Analysts as well as interdisciplinary scientific and administrative staff members in addressing individual postmarket safety concerns for individual products.

Represents the Division on external committees, task forces, and working groups for postmarketing safety initiatives.

Convenes meetings with appropriate parties as needed, such as professional organizations,

industry, academic institutions, other regulatory agencies, and the public, in gathering of information to explore issues surrounding postmarketing safety initiatives to develop plans to enhance the initiative.

Drafts responses to Congressional inquiries concerning such issues related to postmarketing safety initiatives.

Supervisory Responsibilities: Manages functional discipline. Supervises and evaluates staff who serve as experts in their field. Provides occupational specific technical and administrative direction and supervision to staff performing the work and functions of the organizational unit. Obtains resources and identifies strategic objectives for the organization.

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: Physician Series, 602
https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/0600/medical-officer-series-0602/

Education Requirement: General Medical and Healthcare Series, 601
https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/0600/general-health-science-series-0601/

Professional Experience:

- Significant experience in identifying, articulating, addressing, and resolving unique, far-reaching and/or previously unresolved and precedent-setting problems and complex issues.
- Professional knowledge of and skill in applying theories, concepts, principles, and practices of medicine sufficient to serve as a recognized technical authority and consultant in a specialized technology and broad program that affects national and international interests including the well-being of the American public.
- Possession of strong interpersonal and expert written and verbal communications skills to provide advice and guidance to senior management and employees and prepare a variety of written reports and documents.
- Possession of expert analytical, fact-finding, and investigative techniques and skills to carry out the Division's mission.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions that 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
This position requires a security clearance and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent, which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of highly sensitive information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.

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

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

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

Please submit a resume with cover letter by October 22, 2021 to: CDER-OND-Leadership-Employment@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". For questions please contact CDER-OND-Leadership-Employment@fda.hhs.gov. Please reference Job Reference ID: **OND-DDS-1021.**

Announcement Contact

For questions regarding this Cures position, please contact CDER-OND-Leadership-Employment@fda.hhs.gov.

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FDA is an equal opportunity employer.