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 Surveillance and Epidemiology (OSE)

Application Period: June 17, 2022 – July 8, 2022

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: Associate Director for Public Health Initiatives

Series: AD-0601

Location(s): Silver Spring, Maryland

Salary: Starting at $148,484

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

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 streamlined 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 Center for Drug Evaluation and Research (CDER) is responsible for regulating prescription drugs, including new drugs, generic drugs, biological products and biosimilars as well as over-

the-counter drugs (OTC). CDER's drug regulatory responsibilities include premarket review of new drugs and generic drugs; maintenance of the OTC drug monograph system; monitoring of all marketed drug safety and promotion activities; review, monitoring, and enforcement of drug quality during the entire drug life cycle; and ensuring drug products in the market comply with the law.

The Office of Surveillance and Epidemiology is responsible for the functions of (1) post-market evaluation of adverse drug event reports, medication error reports, industry safety submissions, and dissemination of evaluations to appropriate CDER and Agency offices; (2) providing drug risk assessment support, including proprietary name review of new drug applications, for medical review divisions in area of responsibility; (3) providing tracking, monitoring and evaluation of new drugs in areas of responsibility; (4) detecting and signaling serious unlabeled events that require updated labeling; (5) evaluating risk factors associated with serious, labeled events to improve labeling; (6) planning, directing and collaborating in the review of public health data to explore and/or confirm signals and to assess risk; and (7) providing oversight for the monitoring of adverse drug event surveillance strategies within the mission of CDER, including Risk Evaluation and Mitigation Strategies.

This position is in the Immediate Office, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER).

Duties/Responsibilities

As the Associate **Director for Public Health Initiatives**, the incumbent assists the Super Office Director in executing the above responsibilities by serving as the Office's lead scientific expert on Office activities related to complex, multidisciplinary drug safety matters with a broad public health impact. Such matters may include (but are not limited to) the response to the Covid public health emergency (PHE); the response to the nation's opioid/substance use crisis; and Agency or Office initiatives to address particular aspects of important public health concerns such as the misuse and abuse of psychedelic or cannabis-derived drug products.

- Responsible for the development of evidence-based guidance and policy documents which express the Agency's official position on how drug product manufacturers, health care providers, and others involved in any public health initiative must respond to the relevant public health emergency.
- Develops a strategic plan to describe the approach to be taken by OSE staff, often in conjunction with appropriate subject matter experts from other CDER offices in analyzing, assessing, and evaluating data related to the public health emergency (PHE). Develops the approach and gains concurrence on the application of strategic plans (considering feedback from other relevant experts) and obtains commitment of resources to ensure completion within requisite timeframes.

- Identifies or develops epidemiologic approaches to address drug safety and efficacy issues. Provides expert knowledge of pharmacoepidemiology, including emerging methods and data sources in a rapidly evolving field, with mastery sufficient to provide scientific leadership in the review of complex problems, guiding the Division, and others across the Agency, as appropriate. This may include scientific oversight of epidemiological drug safety and efficacy reviews, regulatory research projects, procurement of data resources, and the development of computational software.
- Represents the Office at meetings convened by the Center, Agency, Department, or other Federal agencies on the appropriate public health initiative or emergency response.
- Presents updates of results of analyses on public health emergencies to the FDA Commissioner or other senior officials, as well as answering questions from the public, Center Director, Commissioner, Secretary of HHS, or Members of Congress or their staff on these complex public health initiatives.

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.
- 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. Technical
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:

General Medical and Healthcare Series, AD-0601

Degree: Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U. S. Department of Education at the time the degree was obtained.

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

Desired Education:

Our ideal candidate will possess:

A doctoral-level degree from an accredited institution of higher learning, including Ph.D., M.D., D.V.M., D.D.S., D.M.D., Sc.D., or other research doctoral-degree widely recognized in U.S. academe as equivalent to a Ph.D.

Desired Professional Experience:

Our ideal candidate will possess most or all the following:

- Experience in applying knowledge of the Food, Drug and Cosmetic (FD&C) Act, Code of Federal Regulations and other Agency guidelines and policies pertaining to review of drug and therapeutic biologic applications.
- Experience in applying advanced professional theories, principles, concepts, standards, and methods of pharmacy and/or drug regulatory process sufficient to resolve highly sensitive or ill-defined problems and issues related to novel or complex important public health issues.
- Experience in planning, designing, monitoring, and evaluating complex projects that involve multiple scientific or policy disciplines, that address important public health issues, and/or that extend over significant periods of time (e.g., a year or more).
- Demonstrated experience consolidating scientific opinions and assessments developed by multiple, discrete organizational units into a coherent position consistent with overall FDA policy positions.
- Ability to develop networks and build alliances; collaborates across boundaries to build strategic relationships and achieve common goals.
- Ability to identify and analyze problems; weigh relevance and accuracy of information; generate and evaluate alternative solutions; and make

recommendations.

- Demonstrated ability to communicate and work with staff at all levels of the organization and varying levels of domain expertise.
- Understanding of the public health and public policy issue concerning substance use disorders.

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

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

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

How to Apply: Submit resume with cover letter by **July 8, 2022,** to: OSE-PMAS-Admin-Team@fda.hhs.gov. Candidate resumes may be shared with hiring official 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”. For questions, please contact Amy.Garvin@fda.hhs.gov. Please reference **Job Reference ID: OSE-ADPHI-1**.

How You 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 Amy.Garvin@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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