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)
Controlled Substances Initiatives (CSI)

Application Period: April 1, 2024 - April 22, 2024

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: Supervisory General Health Scientist

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $163,964

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 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 mission of the Office of the Center Director (OCD) is to provide leadership and overall direction to all CDER activities to ensure that the mission of the Center is accomplished. CDER makes 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.

Controlled Substances Initiatives (CSI) helps identify, mitigate, and manage emerging issues with controlled substances through proactive policies and activities to minimize risks associated with problematic use while enabling appropriate access to these products for medical use. CSI collaborates closely with strategic partners across CDER to deliver on these initiatives.

Duties/Responsibilities

As **Supervisory General Health Scientist** for Controlled Substances Initiatives (CSI), the incumbent supervises and leads a staff supporting FDA's efforts to broaden the FDA Opioid priorities in alignment with the U.S. Department of Health and Human Services' (HHS) Overdose Prevention Strategy and FDA Overdose Prevention Strategy. The incumbent provides leadership, direction, and planning for identifying and analyzing emerging issues with non-medical or problematic use of controlled substances as well as to develop strategies and initiatives to address that use in collaboration with the Deputy Center Director for Substance Use and Behavioral Health.

- Provides direct supervision over the controlled substance initiatives staff: plans, organizes, and delegates work to accomplish staff goals; defines roles and responsibilities; evaluates performance and provides feedback; helps to resolve employee issues and disputes; communicates essential information between management and employees; develops team models and norms; and fosters an environment of team engagement in problem solving and continuous improvement.
- Provides subject matter expertise on public health focused approaches to address the problematic use of controlled substances as well as working knowledge of the Controlled Substances Act (CSA) as it relates to the work of the FDA based on scientific and regulatory assessments.
- Oversees the development of policies and programs involving complex and high priority scientific matters affecting the regulation of controlled substances. Identifies problems or issues associated with the Center's approaches to controlled substances, such as opioids, that need additional attention because of nationwide public concern and Agency interest.
- Serves as a public health focused expert on addressing problematic use of controlled substances. Represents FDA and CDER on congressional briefings related to controlled substances and its effects on mental health. Represents FDA at conferences and professional meetings in the U.S. and overseas, before the regulated industry, clinical investigators, and the medical/scientific community on the applicable regulations and policies, to communicate current policy developments at the Agency and to exchange

information with stakeholders.

Supervisory Responsibilities: Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate staff performing the work and functions of the organizational unit. Ensures the Staff's goals, objectives, work plans, and products are in accordance with the organization's strategic plan, mission, vision, and values. Obtains resources, identifies strategic objectives, and establishes goals for the Program.

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:

Supervisory General Health Scientist, AD-0601 Series

Degree: A 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.

Professional Experience:

Our ideal candidate will possess:

- Demonstrates the ability to lead a highly diverse workforce, matrixed and hierarchical teams, including implementation of change management.
- Demonstrates the ability to develop networks and build alliances; collaborate across boundaries to build strategic relationships and achieve common goals.
- Demonstrates ability to apply knowledge of one or more professional fields (e.g., pharmacology, chemistry) and skill sufficient to identify and understand the most difficult, complex, and broad agency regulations and provide executive leadership and guidance in an area that has a major impact on public health.
- Demonstrates knowledge of public health focused principles and practices as they relate to problematic substance use and behavioral health initiatives.
- Possess communication skills, necessary to interact sufficiently with both internal FDA groups, including the Commissioner, and external parties including the press, other HHS and U.S. Government agencies, such as the Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), advocacy organizations, patient groups, and other scientists.
- Experiences in understanding the topics of behavioral health and substance use and how they relate and the impact of substance abuse on mental health and vice versa.
- Demonstrates ability to provide authoritative recommendations and guidance on policies that have broad health implications, concern precedent-setting interpretations, and are industry-wide in effect.

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 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 **April 22, 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”.

Please reference Job Reference ID: **S-22-908-E** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please email CDER-OCD-OEP-Hires@fda.hhs.gov

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