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 Executive Programs (OEP)
Legislative Affairs Staff (LAS)

Application Period: August 28, 2023 – September 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: Public Health Analyst

Series: AD-0685

Location(s): Silver Spring, MD

Salary: Starting at $132,368

Work Schedule: Full Time

Full Performance Band Level: Band D

Cures Band(s): Band D

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 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 Executive Programs (OEP) oversees a variety of Center-wide programs, including executive project management, the Center's executive secretariat function, scientific advisory committees, training, and development, CDER's ombudsman, and program and administrative management.

The Legislative Affairs Staff (LAS) is responsible for ongoing Congressional issue tracking, legislative developments, and Congressional oversight and investigation issues. The staff handling executive correspondence, Congressional hearing preparation, and executive meeting preparation.

Duties/Responsibilities

As a **Public Health Analyst** in the Legislative Affairs Staff (LAS), the incumbent advises officials within CDER on policies and principles to ensure alignment in accomplishing program objectives related to legislative activities; works closely with the LAS Director to develop innovative strategies for legislative engagement on human drugs topics; briefs senior management and managers on legislative matters; and is responsible for the executive preparation of senior management on Congressional matters.

In collaboration with the FDA Office of Policy and Legislation (OPL), and HHS Office of the Assistant Secretary for Legislation (HHS/ASL), the incumbent coordinates CDER legislative affairs activities by developing and managing Congressional interactions to advance the mission of the organization. Coordination of legislative activities involves the analysis of highly technical, scientific, professional, and controversial information on public health legislative matters originating from the CDER Super Offices. The incumbent:

- Applies understanding of the legislative process to coordinate Center's review and response to inquiries on public health policies as they relate to the Center's public health mission. Develops policy briefs (through data collected) and position papers on priority issues for internal and Congressional correspondence/briefings regarding public health policies such as new drug approvals, generic drug approvals, biosimilar approvals, and more, works closely with all levels of CDER, FDA and DHHS to reach a consensus.
- Drafts, edits, and reviews Congressional technical assistance, correspondence, and briefing requests to accurately reflection and communicate Center and Agency priorities align with legislative or proposed bill text.
- Conducts legislative analysis and policy reviews for public health programs to determine alignment with current Center and Agency priorities and make recommendations for integrating public health priorities into legislative activities.
- Manages Congressional inquiries from authorizers and appropriators related to CDER programs and CDER- regulated products. Manages and establishes procedures and controls for the receipt, hand ling, tracking, clearance, cataloging, classifying, suspense, and retrieval of CDER congressional actions. Ensures consistent messaging on legislative

affairs aligns with Center and Agency priorities.
- Leverages program management methodologies to ensure the successful development and execution of briefing material, position papers and correspondence to address public health initiatives and analysis of statutory and regulatory frameworks. Works to achieve consistent approaches in meeting developed short term objectives and integrating long term objectives into legislative activities processes for CDER.

Supervisory Responsibilities: N/A

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:

Public Health Program Specialist, AD-0685 Series:
Major study in public health or other field of study with course work directly related to the work of the position to be filled.

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

Desired Professional Experience:
Our ideal candidate will possess:

- Knowledge of organizational, operational, and programmatic concepts and practices applied by public, private, or nonprofit agencies and organizations engaged in public health or other health-related activities.
- Knowledge of the methods, processes, and techniques used to develop and deliver public health or health-related programs in State and local settings.
- Knowledge of a specialized public health program.
- Knowledge of, and skill in, the application of administrative or analytical methods and techniques necessary for working within the framework of a public health or related organization and carrying out specific program functions.
- Skill in oral and written communications, gathering and conveying information, making oral presentations, and preparing reports, correspondence, and other written materials.
- Conducts studies and performs other analytical work related to the planning, development, organization, administration, evaluation, and delivery of public health programs.

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/Moderate-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 **September 15, 2023,** 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: **T-22-88-2-D** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Crystal Coulter, Management Analyst, Crystal.Coulter@fda.hhs.gov.

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