



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 Compliance (OC)
Office of Unapproved Drugs and Labeling Compliance (OUDLC)

Application Period: September 7, 2023 - September 28, 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 (Special Assistant)

Series: AD-0685

Location(s): Silver Spring, MD

Salary: Starting at \$132,368

Work Schedule: Full-Time

Cures Band(s): Band D

Full Performance Band Level: 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 mission of the Office of Compliance (OC) is to shield patients from poor quality, unsafe and ineffective drugs through proactive compliance strategies and risk-based enforcement actions. CDER OC strives to be a model of efficiency, innovation, and operational excellence. Guided by law and science, the Office makes strategic and risk-based decisions, communicates clearly with all stakeholders, fosters global collaboration, promotes voluntary compliance, and takes decisive action.

The mission of the Office of Unapproved Drugs and Labeling Compliance (OUDLC) is to develop and implement policies and compliance strategies for protecting the public health by assuring compliance with the new drug and misbranding requirements of the Federal Food, Drug and Cosmetic Act.

Duties/Responsibilities

As a **Public Health Analyst (Special Assistant)**, the incumbent serves as a Special Assistant to the OUDLC Director and addresses overreaching issues that impact the development of policies and compliance strategies protecting the public health. In this capacity, the incumbent leads the development and implements projects and initiatives that cut across the office, including those related to unapproved new drugs, misbranded drugs, drug registration and listing, enforcement, and outreach. Given the nature of OUDLC's work to protect the public health by assuring compliance with the new drug and misbranding requirements of the Federal Food, Drug and Cosmetic (FD&C) Act, workload is variable, crosscutting and often complex, requiring directed and urgent action.

- Identifies and assess emerging, standing or precedent-setting issues and their potential or real impact on OUDLC's procedure, policies, activities, and resources. Makes recommendations to OUDLC Director regarding work priorities for the Office, proposing which issues must be addressed immediately and reprioritizing current work to help ensure Office goals are achieved in a timely manner.
- Performs, facilitates, or leads special assignments, which includes data calls and other requests for information, while others may require immediate attention to address situations that develop in critical circumstances or come up in an emergency. These are often complex issues that may involve multiple entities within the Agency, government, Congress, and are driven by the need to protect public health. Assignments may involve multiple inter-personal contacts within Agency and FDA, Federal, State, and local health authorities, the regulated industry, health professionals and the public.
- Develops briefing papers after researching appropriate sources, weighs the probable consequences of various approaches and provides recommendations to high-level officials.
- Researches and prepares written and oral reports on OUDLC Compliance activities to be conveyed throughout CDER's Office of Compliance and/or throughout the FDA. Prepares studies on a variety of topics including relevant legislation, policies, projects, and special

initiatives.

- Monitors OUDLC's activities and attends to emerging problems or issues that affect the direction or outcome of OUDLC goals and objectives.
- Develops solutions or recommendations to modify or change the approach, if needed and presents findings to senior management.
- Performs a variety of substantive activities related to OUDLC public health programs, such as preparing internal and public-facing presentations related to public health issues for the OUDLC Director.
- Coordinates meetings and working groups related to public health issues for OUDLC and collating public health data for OUDLC projects.
- Coordinates projects and participates on teams engaged in implementing plans and programs for initiatives and standards.
- Formulates or influences short and long-range OUDLC goals. Tracks and reports on project status and program development activities. Identifies potential adverse impacts and recommends solutions.
- Reviews and assesses program status and resource requirements of program compliance activities and initiatives. Identifies and advises OUDLC Director of potential problem areas that may adversely impact timelines and proposes solutions to ensure completion of deliverables.

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 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

Degree: Major study in public health or other field of study with course work directly related to the work of the position to be filled.

Or

Specialized Experience

- 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.

For more information, please see: [OPM Occupational Series Qualification Requirements](#).

Desired Education:

Our ideal candidate will possess degree from an accredited institution (B.S., M.S. or other) with major study in public health or other field of study with course work directly related to the work of the position to be filled.

Desired Professional Experience:

Our ideal candidate will possess:

- Ability to apply the Federal Food, Drug, and Cosmetic (FD&C) Act, regulations, guidance, and SOPs to public health and program activities.
- Ability to analyze, evaluate, and make recommendations with respect to methods, practices, and techniques of policy development and project management to manage public health projects and resources.
- Ability to communicate information to others regarding public health and program issues.
- Ability to interpret guidelines and agency policies to advise on program operations, including those leading to evaluation and improvement of complex projects and processes.

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 security clearance was 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 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

All qualified candidates should submit their resume with cover letter and transcripts by **September 28, 2023**, to: CDEROC-OU DLC-Recruitment@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”.

Announcement Contact

For questions regarding this Cures position, please contact CDEROC-OU DLC-Recruitment@fda.hhs.gov. Please reference “CURES Public Health Analyst (Special Assistant)” in the subject when applying or submitting questions.

The U.S. Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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