



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)

Application Period: August 22, 2022 - September 6, 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: Consumer Safety Officer

Series: AD-0696

Location(s): Silver Spring, MD

Salary: Starting at \$126,233

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.

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 (FD&C) Act.

Duties/Responsibilities

As a **Consumer Safety Officer** in the Office of Unapproved Drugs and Labeling Compliance (UDLC), the incumbent serves as a Subject-Matter-Expert (SME) with responsibilities for protecting the public health of U.S. consumers from unapproved and misbranded drug products through the enforcement of compliance laws and regulations. Performs substantive activities in major compliance areas involving difficult, complex, controversial, and precedent setting compliance strategies, cases, regulatory actions, policies, guidances, and outreach activities.

- Identifies, assesses, and evaluates drug compliance issues. Informs, consults with, and advises OUDLC management and other multidisciplinary personnel on drug compliance problems and issues discovered during evaluations. Manages, reviews, and prepares final reports including Agency determinations and findings.
- Works independently and with team members to appropriately manage cases including development of strategic plan for investigations, Agency response, and final disposition. Reports to the Branch Chief on individual work accomplishments, problems, progress in mastering tasks and work processes.
- Uses resources such as the Code of Federal Regulations, the Federal Register, and others, to conduct research regarding established precedents to develop and support compliance actions and policies. Interprets and applies existing policies that effect internal and industry program activities and the marketing of regulated products.
- Conducts briefings, presentations, and meetings for Office with Agency officials and external stakeholders. Attends meetings both within and outside the federal government addressing topics that relates to the Office scope of responsibility.
- Serves, or prepares others to serve, as an expert witness in trials, and Congressional or court hearings where testimony may be challenged by drug researchers, industry, or Congress. Responds to inquiries and provides guidance to other FDA components, industry, state authorities, consumers, and health care professionals.

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:

Consumer Safety Officer, AD-0696 Series

Degree: A bachelor’s or graduate degree from an accredited institution of higher learning. For more information, please visit: [OPM Occupational Series Qualification Requirements](#).

Desired Professional Experience:

Our ideal candidate will possess:

- Experience evaluating and making recommendations with respect to compliance with regulations and other applicable requirements and policies.
- Experience communicating scientific/technical information to others regarding

regulatory compliance issues.

- Skill in interpreting legal or regulatory guidelines and agency policies to advise on program operations.
- Ability to analyze, evaluate, and interpret complex Federal statutes and regulations or related background.
- Ability to meet and deal effectively on behalf of the Center with those persons and organizations having business with or who are influenced by Center programs or related background.
- Mastery and skill in applying expertise in advanced professional theories, principles, concepts, standards, and methods sufficient to conceive and apply experimental theories and new development applications to extend and modify theories, concepts, and assumptions; resolve unique or novel problems, conditions, and issues; and significantly alter standard practices, equipment, devices, processes, and known techniques.
- Ability to communicate in writing and orally to present findings and recommendations; to interact/communicate effectively internally with reviewers, Divisions, Offices, clinical divisions, compliance officials and FDA's nationwide field personnel; and externally with sponsors/applicants, academicians, expert peers in drug regulations, other Federal agencies, state and local governments.
- In-depth and comprehensive knowledge of the recall and drug shortage procedures, regulations, and past precedents combined with knowledge and judgment to determine the regulatory status of a drug product.
- Mastery of the principles, theories, and practices in a field of science or law, practical experience and skills to conduct a critical evaluation the regulatory status of drug products. Conducts consumer safety and public health risk assessments, requiring knowledge and ability to interpret and critically evaluate complex information, data on hazard identification, and consumer safety.

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.

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

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

How to Apply: Submit resume or curriculum vitae with cover letter by **September 6, 2022**, to CDER-OC-IO-PMAS-PMT-OU DLC@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 the CDER OC PMAS OUDLC Team at CDER-OC-IO-PMAS-PMT-OU DLC@fda.hhs.gov. Please reference “Consumer Safety Officer vacancy” in the subject.

Announcement Contact

For questions regarding this Cures position, please contact CDER-OC-IO-PMAS-PMT-OU DLC@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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