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: May 11, 2023 – May 25, 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: Office Director (Supervisory Consumer Safety Officer)

Series: AD-0696

Location(s): Silver Spring, MD

Salary: Starting at: $213,491

Work Schedule: Full-Time

Cures Band(s): Band G

Full Performance Band Level: Band G

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 compensated 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 and prescription drugs, including biological therapeutics and generic drugs.

The mission of the Office of Compliance (OC) is to shield the public from poor-quality, unsafe, and ineffective drugs through proactive compliance strategies and risk-based enforcement actions. CDER Compliance strives to be a model of efficiency, innovation, and organizational excellence. CDER Compliance makes strategic and risk-based decisions that are guided by law and science to communicate clearly with stakeholders, foster global collaboration, promote voluntary compliance, and take 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. OUDLC engages in strategic, risk-based, compliance and regulatory activities to shield patients from poor quality, unsafe and ineffective drugs through proactive compliance strategies and risk-based enforcement actions.

Duties/Responsibilities

As the **Office Director (Supervisory Consumer Safety Officer)** for the Office of Unapproved Drugs and Labeling Compliance (OUDLC), the incumbent is expected to manage and direct the development and implementation of the Agency's human unapproved drug and enforcement programs.

- Advises the Super Office Director and other senior Agency officials on compliance matters of major significance pertaining to unapproved prescription drugs, over-the-counter drugs, fraudulent drugs, as well as drug registration and listing.

- Provides leadership to subordinates and oversight of operations; leads engagement with stakeholders.

- Develops short/long term goals, policy, guidance, and innovative compliance strategies; and lead efforts to achieve strategic objectives and goals.

- Develops and implements policies, surveillance activities, compliance strategies, regulatory actions, and enforcement actions associated with new drug and labeling requirements of the Federal Food, Drug and Cosmetic Act (FD&C) Act.

- Oversees and implements activities related to fraudulent drug products, including establishing proactive strategies to respond to new and emerging products and public health threats. Provides cross-Agency and government coordination for implementation of regulatory and compliance strategies as well as taking enforcement actions.

- Oversees and coordinates evaluation of compliance with the statutory and regulatory

framework of over-the-counter (OTC) drugs, including under the Cares Act. Provides Center coordination with ORA Field Offices and OCC for implementation of compliance and enforcement actions.

- Develops and implements compliance strategies, programs, and policies to ensure that all prescription drugs marketed in the United States meet applicable new drug requirements and are properly labeled. Engages in strategic, risk-based, regulatory and enforcement activities to minimize consumer exposure to unsafe and ineffective drug products that do not meet labeling and approval requirements while preserving patient access to medically necessary drugs.

- Develops comprehensive policy and procedural guidelines for handling compliance and enforcement actions related to human unapproved drugs. Reviews and approves legal actions in cases where authority has not been delegated to the field, where guidelines have not yet been established, and cases of national scope requiring headquarters coordination.

- Represents the Super Office Director in meetings with the Commissioner and other Senior Agency officials on compliance matters of major significance involving unapproved drugs. Represents the Center in meetings with top level representatives of other Federal and State agencies to obtain their cooperation on compliance matters of mutual interest. Engages with stakeholders, including top level leaders of regulated industries to promote compliance.

Supervisory Responsibilities: Manages several multi-disciplinary programs, providing leadership and management oversight to a component Office of 70 employees, including direct supervision of direct reports in the Immediate Office. These include scientific, legal, professional, technical, administrative, and clerical personnel ranging in grade from supervisory positions to entry levels.

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:
Consumer Safety Series, AD-0696:
Degree: A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work. The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming. 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.

OR

Combination of education and experience courses consisting of at least 30 semester hours in the fields of study described in paragraph above, plus appropriate experience or additional

education.

Qualifying Experience: For Band A and above, in addition to the licensure and educational requirements described above, applicants must have: Qualifying experience involves enforcing laws and regulations to protect consumers from foods, drugs, cosmetics, fabrics, toys, equipment, and household products that are defective, dangerous, impure, unwholesome, ineffective, or improperly or deceptively labeled or packaged.

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

Desired Professional Experience:
Our ideal candidate will possess:

- An advanced degree from an accredited institution, including M.S., Ph.D., Pharm.D., J.D., or similar.

- Demonstrated experience in regulatory surveillance, compliance, and policy development, which includes a background in a scientific, technical, or legal field.

- Demonstrated experience and ability to manage organizations with a regulatory, compliance or enforcement mission. Experiences and abilities should include:
  1. Proficient ability to communicate and collaborate with staff at all levels.
  2. Demonstrated experience in change management and strategic planning; and
  3. Ability to apply organizational awareness of internal and external factors that impact the work of an organization.

- Demonstrated experience in the enforcement of federal laws and regulations, including the Food, Drug and Cosmetic (FD&C) Act and regulations applying to human drugs.

- Demonstrated ability to identify and analyze complex problems, generate, and evaluate alternative solutions, and make evidence-based decisions.

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 qualifications 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 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 in PDF format by **May 25, 2023,** to: FDACDEROC_Recruit@fda.hhs.gov. Candidate resumes may be shared with hiring officials within 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 submit your inquiry with email subject title ***"CDER-OC-OUDLC Office Director"*** and contact FDACDEROC_Recruit@fda.hhs.gov.

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

FDA is an equal opportunity employer.