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 Drug Security, Integrity, and Response (ODSIR)
Division of Global Drug Distribution and Policy (DGDDP)

Application Period: October 3, 2023 - October 17, 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: Consumer Safety Officer

Series: AD-0696

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 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 for Office of Drug Security, Integrity, and Response (ODSIR) is to protect the integrity of the global supply chain throughout the drug lifecycle to minimize consumer exposure to unsafe, ineffective, and poor-quality drugs. The Office consists of two Divisions, overseeing the Imports, Exports, Recalls, Incidence Management, Online Internet Sales, and the Drug Supply Chain Security Act (DSCSA) programs.

The Division of Global Drug Distribution and Policy (DGDDP) serves as CDER's focal point for Imports operations, surveillance, compliance, policy and analytics and Exports operations, surveillance, compliance, and policy. DGDDP has the following two branches: Imports Compliance Branch (ICB) serves as FDA and CDER's focal point for operational, compliance and policy issues related to the import of drugs including operations, surveillance, sampling, and work planning. Exports Compliance Branch (ECB), serves as FDA and CDER's focal point for all operational and compliance issues related to the export of drugs including the Exports Compliance program, reviewing of requests for and issues, export certificates, when appropriate.

Duties/Responsibilities

As a **Consumer Safety Officer,** the incumbent serves in the DGDDP Immediate Office and will be responsible for providing support and leading strategic planning activities and process improvement efforts pertaining to imports and exports.

- Uses knowledge of and experience with the programmatic compliance programs, laws, regulations, guidance, and policy to spot trends impacting policy matters within the scope of the Division.
- Ensures workgroup meetings are collaborative and managed using project management practices and principles documenting project plan, expected outcomes including deliverables and milestones. Prepares and finalizes process flows, SOPs and monitors IT system changes using knowledge and experience with the programmatic compliance programs, laws, regulations, guidance, policies, and public

health initiatives.

- Identifies viable and innovative solutions to program area challenges and makes enhancements to processes as identified.
- Updates and monitors ODSIR's established strategic plans for import and export programs. Ensures that strategic objectives are appropriately mapped to specific outcomes and aligns with changes in the ODSIR, OC and Center strategic plans.
- Maintains tracking and updating of all projects using the Project Portfolio Management system. Prepares and presents periodic updates to the Division Director and others on a set schedule and ad hoc basis as needed. Ensures all Branch Chiefs, project leads, and other stakeholders are routinely provided progress updates.
- Informs and assists in the development and implementation of high level and high visibility special projects. In this capacity, the incumbent will work collaboratively with ODSIR leadership and other internal Center offices and ORA to assist in the development and implementation of new and existing initiatives, strategies, and policies in the imports and exports context. The incumbent may also be required to engage external stakeholders such as the World Health Organization on program projects.
- Manages outreach activities for the Division across all programs.

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, AD-0696 Series

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

Professional Experience:
Our ideal candidate will possess:

- Demonstrated experience and ability to review, assess, and enforce 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.
- Ability to apply knowledge of enabling legislation, policies, implementing regulations and procedures, organizational structures, and interrelationships of compliance organizations and programs with each other in relation to area of responsibility.
- Ability to apply knowledge of and skill in selecting, adapting, and applying investigative methods and negotiating techniques.
- Ability to apply knowledge of written and verbal communication practices and principles to prepare and present written reports, findings, and recommendations. Demonstrated experience and ability to communicate scientific/technical information to others regarding regulatory compliance issues.
- Experience applying the Federal Food, Drug, and Cosmetic Act to drug compliance/enforcement activities, and related regulatory and quality assurance activities.
- Demonstrated experience and ability to review, evaluate and make recommendations

with respect to compliance with regulations and other applicable requirements and policies.
- Ability to interpret legal or regulatory guidelines and Agency policies to advise on program operations.
- Ability to provide guidance and consultation to enforce regulatory objectives.

Desired Professional Experience:
Our ideal candidate will possess:

- A strong background in Quality Management is preferred.
- Experience with the FDA Imports and/or Exports programs is beneficial
- Experience applying the Food, Drug and Cosmetic Act (FDCA) to drug compliance/enforcement activities, and related regulatory and quality assurance activities is beneficial
- 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 regulatory guidelines and agency policies to advise on program operations
- Skill in providing guidance and consultation to enforce regulatory objectives

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

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

Submit resume or curriculum vitae with cover letter by **October 17, 2023** to: CDER-OC-ODSIR-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: CDER-OC-ODSIR-RECRUITMENT@fda.hhs.gov. Please reference Consumer Safety Officer AD-0696-D for DGDDP in the subject line when applying or submitting questions.

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