Title 21 Vacancy Announcement
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)

Application Period: 02/11/2022-02/25/2022

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. 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.

Duties/Responsibilities

As a Consumer Safety Officer, the increment provides technical support within the ODSIR Immediate Office (IO) for the operation and integration of Drug Supply Chain Security Act (DSCSA) program requirements by 2023. This includes, but is not limited to supporting the full implementation and operationalization of DSCSA requirements for licensing of wholesale drug distributors (WDDs) and third-party logistics providers (3PLs), and the enhanced drug security system.

Provides support for leveraging FDA enterprise systems and analytics to enhance ODSIR's operational abilities to secure the drug supply chain.

Performs substantive activities related to policy guidance, internal improvement projections, post-market safety, and surveillance and enforcement. Fully engage in efforts to drive efficiency and effectiveness in these areas.

Serves as principal scientific advisor in major areas related to drug security, distribution, and supply chain integrity, enforcement, surveillance, and outreach, and performs substantive work with a multiplicity of unprecedented and complex scientific topics, including, but not limited to: human drugs, adulteration provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act), emerging technologies, new regulations, and scientific policies.

Assesses, evaluates, and prioritizes drug compliance issues, and marketed product defects. Informs, consults with and advises Center and Office management, Office of Regulatory Affairs (ORA), Agency level managers and other multidisciplinary personnel on difficult and complex regulatory, scientific and drug compliance problems and issues discovered during evaluations. Oversees, monitors, reviews and prepares final reports including Agency determinations and findings.

Evaluates, identifies, and addresses significant problems and issues in areas where nominal policy guidance exists, and requires prompt remediation. Exercises subject matter expertise/knowledge/experience in resolving problems, modifying procedures and developing and implementing guidance, some of which form the basis for formal regulatory decision-making and policy direction. Formulates, develops and presents expert findings and recommendations internally and externally, to ORA, regulatory reviews and clinical divisions. Provides expert authoritative advice, recommendations, guidance and assistance in addressing

unusually difficult and/or complex problems.

Confers with and advises the Office of the FDA Commissioner, CDER Center and Office Directors on potential issues and impacts associated with emerging related to drug manufacturing and product consistency. The employee serves as an authority for often controversial, highly sensitive and complex issues that may have national/international implications (e.g., pharmaceutical ingredient supply chain safety).

Serves as a representative of FDA and CDER by conducting briefings, presentations, and meetings with regulated industry representatives, trade organizations, academic, health professional groups and organizations. Represents FDA on interagency, national, and international committees and forums and represents CDER at professional meetings with regulated industry and with Federal and State regulatory counterparts and agencies (e.g., Center for Disease Control, State Departments of Health; US Justice Department). Represents FDA and CDER by participating on internal and external working groups, national tasks forces, and scientific symposia and public workshops.

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

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 education must have been obtained at a college, university, or an accrediting body recognized by the Secretary, U.S. Department of Education at the time the degree was obtained.

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.

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. OPM Occupational Series Qualification Requirements.

Desired Education: N/A

Professional Experience:

- Technical and scientific expertise in drug product supply chain integrity and security, and FDA laws and compliance regulations
- Demonstrated experience applying the Food, Drug and Cosmetic Act (FDCA) to drug compliance/enforcement activities, and related regulatory and quality assurance activities.

- Demonstrated experience evaluating and making recommendations with respect to compliance with regulations and other applicable requirements and policies.
- Demonstrated experience communicating scientific/technical information to others regarding regulatory compliance issues.
- Skilled in interpreting legal or regulatory guidelines and agency policies to advise on program operations.
- Skilled in providing guidance and consultation to enforce regulatory objectives.

Desired Professional Experience: N/A

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.

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

Submit resume or curriculum vitae with cover letter by **February 24, 2022** to: CDER-OC-ODSIR-Recruitment@fda.hhs.gov. Candidate resumes may be shared with hiring official within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions, please contact CDER-OC-ODSIR-Recuritment@fda.hhs.gov.
Please reference Job Reference ID: T-21-393-D.

Announcement Contact

For questions regarding this Cures position, please contact CDER-OC-ODSIR-Recruitment@fda.hhs.gov

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