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 Compounding Quality and Compliance (OCQC)
Division of Compounding I and II

Application Period: 7/12/2021-7/21/2021

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 (CSO)

Series: AD-0696

Location(s): White Oak, Silver Spring, MD

Salary: Starting at $72,750 (Band A), $87,198 (Band B), $103,690 (Band C)

Work Schedule: Full-Time

Cures Band(s): Bands A, B and C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

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 are 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.

Duties/Responsibilities

Responsible for supporting a program function on a Team that resides within a Branch in one of two Divisions of Compounding in the Office of Compounding Quality and Compliance. The work of the Divisions includes the following functions:

- Performs and traces investigations involving complaints and injuries or deaths associated with compounding drug products regulated by the FDA
- Analyzes information applying scientific and regulatory knowledge and technical investigations requiring coordination, insight, and knowledge in application of procedures and processes involving compliance, regulation, and enforcement actions relating to compounding drug products
- Reviews recommendations for potential administrative and judicial actions related to compounded drugs under the Food Drug & Cosmetic Act (FD&C) to ensure consistency and adherence to FDA policy
- Provides enforcement decision and compliance strategies based on review of evidence of violations, compliance policy, public health risks, and availability

Band A:

- Participates in technical reviews and evaluates compounders where new or unusual features are present. Collaborates with staff on the reviews and analysis of initial investigations and inspections of establishments in the area of assigned responsibility and prepares draft report.
- Works closely with peers and team lead to conduct scientific reviews as to how the investigation should proceed, when an investigation is complete or what additional work may be required.
- Reviews summaries and integrated discussions of scientific data submitted for review and other available information regarding compounders.

Band B:

- Conducts activities in major critical strategic, risk-based compliance and regulatory actions to minimize consumer exposure to unsafe, ineffective, and poor-quality compounded drug products.
- Applies currently accepted technical scientific methods within OCQC on all significant issues related to the operation of the compounding program and assesses medical products as it pertains to OCQC's compliance program.
- Participates in scientific reviews of compounding drug data for scientific or regulatory issues involving medical products. Prepares draft summaries and integrated discussions of scientific data submitted for review and other available information.

- Works on inspectional problems which involve a combination of scientific and regulatory responsibilities.

Band C:

- Acts as an expert on a specialty area of human drug compounding and ensures uniform interpretation of standards.
- Performs substantive activities in major critical risk-based compliance and regulatory areas to minimize consumer exposure to unsafe, ineffective, and poor quality compounded drug products.
- Directs and works on the most difficult, controversial and complex inspectional problems which involve a combination of scientific and compliance responsibilities.
- Provides substantive technical scientific guidance within OCQC on all significant issues related to the operation of the compounding program and assesses medical products as it pertains to OCQC's compliance program

Supervisory Responsibilities: None

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.

In order 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: Minimum Education Requirement: Meets the Office of Personnel Management (OPM) Individual Occupational Requirements (IOR) for Consumer Safety Series, 0696.

Specialized Experience:

To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the grade level of the position. 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.

Desired Professional Experience:

Band A

- Knowledge of the 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; the application of the FD&C Act to drug compliance/enforcement activities, and related regulatory and quality assurance activities; how to evaluate and make recommendations with respect to compliance with regulations and other applicable requirements and policies.
- Ability to communicate scientific/technical information to others regarding regulatory compliance issue, and to interpret legal or regulatory guidelines and Agency policies to advise on program operations.

Band B

- Experience and ability to 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; to apply the FD&C Act to drug compliance/enforcement activities, and related regulatory and quality assurance activities, to evaluate and make recommendations with respect to compliance with regulations and other applicable requirements and policies, and to communicate scientific/technical information to others regarding regulatory compliance issues.
- Ability to interpret legal or regulatory guidelines and Agency policies to advise on program operations, and to provide guidance and consultation to enforce regulatory objectives.

Band C

- Demonstrated experience and ability to 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; to apply the FD&C Act to drug compliance/enforcement activities, and related regulatory and quality assurance activities; to evaluate and make recommendations with respect to compliance with regulations and other applicable requirements and policies, and to communicate scientific/technical information to others regarding regulatory compliance issues.
- Expert ability to interpret legal or regulatory guidelines and Agency policies to advise on program operations, and to provide 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:

This position requires a Non-Sensitive/Low Risk (A/B) or Medium Risk (C) security clearance. 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.

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 with cover letter and transcripts by 7/21/21 to: CDER-OC-COMPOUNDING-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". Candidates should reference the Band(s) they are applying for in the application.

Announcement Contact

For questions regarding this Cures position, please contact CDER-OC-COMPOUNDING-RECRUITMENT@fda.hhs.gov. Please reference "CSO Band A/B/C."

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