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 Manufacturing Quality (OMQ)

MULTIPLE VACANCIES

Position: Consumer Safety Officer

Pay Plan-Series: AD-0696

Location(s): Silver Spring, MD

Travel Requirements: 25% or less

Application Period: March 3, 2021-March 19, 2021

Salary: Starting at $103,690 (CURES Bands C and D)

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: Relocation expenses will not be authorized.

Special Notes: This position is being filled under an excepted 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 the authority. Additional information on 21st Century Cures Act can be found here.

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 and prescription drugs,

including biological therapeutics and generic drugs. The CDER Office of Compliance (CDER OC) mission is to shield patients from poor quality, unsafe and ineffective drugs. The Office of Manufacturing Quality (OMQ) develops and implements compliance and enforcement policies and actions to protect patients from firms whose quality standards and practices may pose a significant risk to public health. The CDER OC Office plans, develops, and directs compliance and enforcement strategies and actions that are patient-focused and risk-based to secure the safety and quality of the nation's drug supply.

Position Summary:

The **Consumer Safety Officer** serves as a scientific advisor for case development, compliance strategies, and regulatory actions, including enforcement, relating to medical drug products, and performs substantive work with a multiplicity of unprecedented and complex scientific topics, including, but not limited to: human drugs, adulteration provision of the Food, Drug, & Cosmetic (FD&C) Act, emerging technologies, new regulations and scientific policies. Provides expert authoritative advice, guidance and recommendations on drug compliance policies, programs, processes, and proceedings. This position can be performed throughout the OMQ Divisions, Branches, Staff and Immediate office.

Supervisory responsibilities: N/A

Duties/Responsibilities (Band C):

The incumbent will serve in a developmental capacity to eventually perform the Band D master professional duties. Work assignments are designed to introduce the full range of duties and responsibilities required for the Full Band Advancement (Band D). Responsibilites include:

Reviews recommendations for potential administrative and judicial actions based on adulteration charges 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

Provides scientific and technical input on compliance issues and in regulatory meetings to ensure consistency of interpretation of Current Good Manufacturing Practices (CGMPs); provides technical and scientific expertise to address significant manufacturing problems or quality defects and collaborates with other regulatory partners to develop and execute compliance programs and actions related to manufacturing quality.

Provides expertise in Current Good Manufacturing Practices (CGMP) compliance/regulatory issues related to manufacturing of medical products. Performs substantive activities in major, critical compliance areas involving potential administrative and judicial actions, enforcement decisions and compliance strategies, compliance and regulatory issues related to Current Good

Manufacturing Practices, manufacturing problems or quality defects, and compliance programs, actions, and assignments related to manufacturing quality. Reviews recommendations for potential administrative and judicial actions based on adulteration charges under the FD&C Act to ensure consistency and adherence to FDA policy, provide enforcement decision and compliance strategies based on review of evidence of violations, compliance policy, public health risks, and availability.

Evaluates, identifies and addresses significant problems and issues in areas where nominal policy guidance exists, and requires prompt remediation. Exercises scientific expertise and knowledge in resolving problems, modifying procedures and developing and implementing guidance, some of which form the basis for formal regulatory decision-making and policy direction.

Provides accurate assessment of the state of compliance of a firm or corporation on regulatory compliance and enforcement and confers with and advises the FDA Office of the Commissioner, CDER Center and other Office Directors on potential issues and impacts associated with drug manufacturing and medical product consistency.

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.

Duties/Responsibilities (Band D):

Duties and Responsibilities outlined in Band C above.

Serves as a technical scientific lead in one or more major areas related to drug quality and manufacturing and CGMP compliance and performs substantive work with a multiplicity of unprecedented and complex scientific topics, including, but not limited to: human drugs, adulteration provision of the FD&C Act, emerging technologies, new regulations and scientific policies.

Provides subject matter expert in CGMP compliance/regulatory issues related to manufacturing of medical products. They review recommendations for potential administrative and judicial actions based on adulteration charges under the FD&C Act to ensure consistency and adherence to FDA policy, provide enforcement decision and compliance strategies based on review of evidence of violations, compliance policy, public health risks, and availability.

Performs substantive technical input to major, critical compliance CGMP areas involving potential administrative and judicial actions, enforcement decisions and compliance strategies, compliance and regulatory issues related to Current Good Manufacturing Practices,

manufacturing problems or quality defects, and compliance programs, actions, and assignments related to manufacturing quality.

Exercises subject matter expertise and knowledge in resolving problems, modifying procedures and developing and implementing guidance, some of which form the basis for formal regulatory decision-making and policy direction. Evaluates, identifies and addresses significant problems and issues in areas where nominal policy guidance exists, and requires prompt remediation.

Advises the FDA Office of the Commissioner, CDER Center and other Office Directors on potential issues and impacts associated with drug manufacturing and medical product consistency.

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. Click here to find out additional information about the Equal Employment Opportunity (EEO) for federal employees & job applicants.

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.

Professional Experience/Desirable Qualifications*:

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, and:

• Experience in applying the Food, Drug and Cosmetic Act (FDCA) to drug compliance/enforcement activities, and related regulatory and quality assurance activities.
• Experience in evaluating and making recommendations with respect to compliance with regulations and other applicable requirements and policies related to CGMPs
• Experience in 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.
• Skill in providing guidance and consultation to enforce regulatory objectives.

**Please indicate in your resume where you have gained this experience.*

Key requirements will include:

Education Requirement (AD-0696):

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.

Or a combination of education and experience--courses consisting of at least 30 semester

hours in the fields of study described in the paragraph above, plus appropriate experience or additional education.

Conditions of Employment:

1. **Security Clearance**:

If not previously completed, a background securityinvestigation 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.

2. **Ethics Requirements**:

This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

3. **How to Apply:**

Please submit resume or curriculum vitae with cover letter by March 19, 2021**,** to CDER OC PMAS staff at CDER-OC-OMQ-Recruitment@fda.hhs.gov. Candidate resumes may be shared with other hiring officials in 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-OMQ-Recruitment@FDA.HHS.GOV.

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

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