TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Compliance (OC)
Office of Manufacturing Quality (OMQ)

Position: Consumer Safety Officer

Series: AD-0696

Location(s): Duty station negotiable upon selection

Travel Requirements: 25% or less

Application Period: November 6, 2020- November 20, 2020

Salary: Starting at $102,663 (Band C)

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy. <change to no relocation expenses will be paid. >

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 be 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 that all human and animal drugs, and 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 Office of Compliance (OC) shields 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 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. OMQ 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 and guides compliance strategies and enforcement actions and ensures uniform interpretation of drug manufacturing quality standards and systems. OMQ collaborates with foreign scientific regulators in the development and execution of compliance and enforcement strategies related to drug quality standards and systems and collaborates with other agency scientists and medical professionals to ensure the uniform application of risk-based, patient-focused compliance and enforcement policies and actions.

Position Summary:
This position reports to a Branch Chief within a Division in the Office of Compliance (OC), Office of Manufacturing Quality (OMQ). Serves as a Consumer Safety Officer for case development, compliance strategies, and regulatory actions, including enforcement, relating to 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.

Supervisory responsibilities: No Supervisory responsibilities

Duties/Responsibilities:

The incumbent is responsible for supporting a program function on a Team that resides within a Branch in one of three Divisions of Drug Quality (DDQ I-III), OMQ. The work of the Divisions includes the following functions: 1) 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; 2) provides enforcement decision and compliance strategies based on review of evidence of violations, compliance policy, public health risks, and availability; 3) participates with other FDA Offices, Divisions, and districts on compliance issues and in regulatory meetings to ensure consistency of interpretation of Current Good Manufacturing Practices (CGMPs); 4) provides expertise to address significant manufacturing problems or quality defects and 5) collaborates with international regulatory partners.

Performs substantive activities in major critical compliance areas related to drug manufacturing and assessment of medical products within the Office of Manufacturing Quality that includes involving

difficult, complex, controversial, and precedent setting quality evaluations; guidance and policy development; international agreements; inspections; surveillance evaluation; drug recall evaluation; and manufacturing shortage mitigation.

Prepares comprehensive summaries and integrated discussions of scientific data (i.e., inspection and investigations) submitted for review and other available information. Submits regulatory recommendations and conclusions for concurrence by senior scientific staff and writes comprehensive analytical reports from scientific investigations studies and projects.

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. Coordinates monitors, reviews and prepares final reports including Agency determinations and findings. Attends and participates in meetings and conferences with senior level officials from regulated industry.

Meets with industry representatives to exchange information and to provide advice and guidance regarding those aspects of review with deficiencies. Answers inquiries from other Federal, State or local agencies, foreign missions, Industry, and importers regarding interpretations of Agency-enforced laws and regulations, case status, and enforcement policies.

Confers with and advises OMQ and OC management and other Office Directors on potential issues and issues associated with drug manufacturing and product consistency. The incumbent may serve as a subject matter expert for often controversial, highly sensitive and complex issues that may have national/international implications.

Evaluates, identifies and addresses significant problems and issues in the area of drug manufacturing and identifies issues that require 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.

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 learn more about 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. 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.

- Experience applying the Food, Drug and Cosmetic Act (FD&C) to drug compliance/enforcement activities and related regulatory and quality assurance activities.
- 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 legal or regulatory guidelines and agency policies to advise on program operations.
- Skill in providing guidance and consultation to enforce regulatory objectives.

Qualifications:

Master of occupational specialty. Skilled in applying knowledge to all occupation-related duties and responsibilities. May specialize in one or more aspects of occupational specialty.

Mastery 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.

Comprehensive knowledge of and skill in selecting, adapting, and applying investigative methods and

negotiating techniques.

Knowledge of written and verbal communication practices and principles to prepare and present written reports, findings, and recommendations; develop analyses that are used for disposition of cases, testimony to be presented, presentations and as instruments for negotiations; conduct negotiations with industry representatives and other government agencies; and, develop formal training programs.

Increasing abilities in current primary skillsets of occupational specialty.

Mastery and skill in applying expertise in advanced professional theories, principles, concepts, standards, and methods sufficient to conceive and apply experimental theories and new development applications to extend and modify theories, concepts, and assumptions; resolve unique or novel problems, conditions, and issues; and significantly alter standard practices, equipment, devices, processes, and known techniques. Expert knowledge of broad operating programs to advise senior colleagues and agency officials and manages significant projects that represent an important segment of the agency's operating programs.

Broad knowledge of a variety of various scientific and technical disciplines are necessary to carry out tasks related to the compliance of FDA regulations.

Knowledge of current primary skills of occupational specialty.

Mastery knowledge of a category of products or a functional specialty which is distinctly more difficult to work with because of the medicine, science, and/or technologies involved and because the legal and regulatory concepts necessary to enforce the law are correspondingly more complex and/or unprecedented.

Desirable Education:

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

Applicants must meet one of the following requirements:

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.

OR
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.

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.

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.

Conditions of Employment:

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 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.

How to Apply: Submit resume or curriculum vitae with cover letter **by November 20, 2020** to: CDER-OC-OMQ-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". 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.

FDA is an equal opportunity employer.