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)
Division of Drug Quality III (DDQIII)
Office of Manufacturing Quality (OMQ)

Position: Consumer Safety Officer

Series: AD-0696

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

Travel Requirements: Up to 25%

Application Period: 9/18/2020 to 10/2/2020

Salary: Starting at $121,316 (Cures Band D)

Area of Consideration: United States Citizens or Nationals

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

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 paid under the provisions of the authority. Additional information on 21st Century Cures Act can be found at: https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act

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 Center for Drug Evaluation and Research (CDER), is responsible for regulating prescription drugs,

including new drugs, generic drugs, biological products and biosimilars as well as over-the-counter drugs (OTC). CDER's drug regulatory responsibilities include premarket review of new drugs and generic drugs; maintenance of the OTC drug monograph system; monitoring of all marketed drug safety and promotional activities; review, monitoring and enforcement of drug quality during the entire drug life cycle; and ensuring drug products in the market comply with the law.

The CDER Office of Compliance (CDER OC) mission 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. CDER OC makes strategic and risk-based decisions that are guided by law and science to foster global collaboration, promote voluntary compliance and takes decisive and swift actions to protect patients.

Position Summary:

Serves as a Consumer Safety Officer and principal scientific advisor for case development, compliance strategies, and regulatory actions, including enforcement, relating to compounded 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.

Duties/Responsibilities:

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

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.

Attends and participates in meetings and conferences with senior level officials from regulated industry to discuss and resolve problems and provides accurate assessment of the state of compliance of a firm or corporation on regulatory compliance and enforcement.

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.

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.

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.
- 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.

Required Education:

Minimum Education Requirement: Meets the Office of Personnel Management (OPM) Individual Occupational Requirements (IOR) for Consumer Safety Series, 0696. Please review the entire IOR to confirm the minimum education requirements at the following link: Consumer Safety Series, 0696.

Desirable Education:

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 paragraph A 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.

Conditions of Employment:

Security Clearance: Non-Critical 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.

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: http://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/default.htm.

How to Apply: All qualified candidates should submit a curriculum vitae and cover letter describing why you are uniquely qualified for this position, including how you possess the desired experience and qualifications identified above, electronically to CDEROC_recruit@fda.hhs.gov, c/o, CDER Office of Compliance Program Management and Analysis Staff (PMAS). For questions please contact the CDER OC PMAS at CDEROC_recruit@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.