Title 21 Vacancy Announcement
U.S. 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 Unapproved Drugs and Labeling Compliance (OUDLC)

Application Period: July 24, 2023 - August 24, 2023

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: Regulatory Counsel

Series: AD-0301

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 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, OC makes strategic and risk-based decisions, communicates clearly with all stakeholders, fosters global collaboration, promotes voluntary compliance, and takes decisive action.

The mission of the Office of Unapproved Drugs and Labeling Compliance (OUDLC) is to develop and implement policies and compliance strategies for protecting the public health by assuring compliance with the new drug and misbranding requirements of the Federal Food, Drug and Cosmetic Act. OUDLC engages in strategic, risk-based, compliance and regulatory activities to shield patients from poor quality, unsafe and ineffective drugs through proactive compliance strategies and risk-based enforcement actions.

Duties/Responsibilities

As a **Regulatory Counsel** in the Office of Unapproved Drugs and Labeling Compliance (OUDLC), the incumbent serves as a Subject Matter Expert (SME) with responsibilities for protecting the public health of U.S. consumers from unapproved and misbranded drug products through the enforcement of compliance laws and regulations. In this capacity, the incumbent performs substantive activities in major compliance areas involving difficult, complex, controversial, and precedent setting compliance strategies, cases, regulatory actions, policies, guidances, and outreach activities.

- Provides regulatory expertise related to unapproved drug products and performs substantive work with a multiplicity of unprecedented and complex legal and policy issues, including, but not limited to human drugs, misbranding provision of the Federal Food, Drug, and Cosmetic (FD&C) Act, emerging technologies, new regulations, and regulatory policies. As SME, the employee provides authoritative advice, guidance and recommendations on drug compliance policies, programs, processes, and proceedings.
- Identifies, assesses, and evaluates drug compliance issues. Informs, consults with, and advises OUDLC management, Office of Regulatory Affairs (ORA), and other multidisciplinary personnel on regulatory, scientific and drug compliance problems and issues discovered during evaluations. Manages, reviews, and prepares final reports including Agency determinations and findings.
- Works independently and with team members to appropriately manage cases including development of strategic plan for investigations, Agency response, and final disposition. The incumbent uses knowledges of a variety of disciplines to carry out assigned tasks, Reports to the Branch Chief on individual work accomplishments, problems, progress in mastering tasks and work processes.
- Makes independent scientific and regulatory judgments on cases. Analyzes problems and develops enforcement and regulatory strategies to address drugs that are

misbranded, unapproved, or violate other aspects of the Federal FD&C Act using a risk-based methodology.

- Uses resources such as the US Code, Code of Federal Regulations, the Federal Register, and others, to conduct research regarding established precedents to develop and support compliance actions and policies. Interprets and applies existing policies that effect internal and industry program activities and the marketing of regulated products.
- Collaborates with other OUDLC SMEs to develops policy, regulatory and legal analyses. Coordinates and prepares responses to inquiries from industry, congressional, FDA, and other entities pertaining to FDA's enforcement of laws, regulations, case status, and enforcement policy. May be required to serve as a resource to FDA's Office of Chief Counsel (OCC) in developing cases for legal proceedings. As a subject matter expect, the incumbent may be required to serve as a Federal witness in legal proceedings.
- May conduct briefings, presentations, and meetings for Office, CDER, and Agency officials, regulated industry representatives, trade associations, health professional organizations/groups, and academia.
- Provides guidance and/or training to regulatory specialists and other professionals within FDA on matters relating to expertise level.

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:
Regulatory Counsel - AD 0301 Series

For more information, please see: OPM Occupational Series Qualification Requirements.

Desired Education: Our ideal candidate will possess a juris doctorate degree from an accredited institution of higher learning.

Desired Professional Experience:
Our ideal candidate will possess:

- Master of occupational specialty. Skilled in applying knowledge to all occupation-related duties and responsibilities.
- Expert knowledge of the various titles of law applicable to the Agency's mission, Federal law governing or affecting the program, Federal regulations, and significant national developments in the field. These laws may include, but are not limited to, the Federal Food, Drug, and Cosmetic (FD&C) Act and the Public Health Service Act or related types of legislation.
- Mastery of other pertinent regulatory information in agency manuals, reference systems, directives, issuances, precedent decisions, court decisions, and commercial publications or a similar background.
- Ability to analyze, evaluate, and interpret complex Federal statutes and regulations or related background. Ability to meet and deal effectively on behalf of the Center with those persons and organizations having business with or who are influenced by Center programs or related background.

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 security clearance was 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 or curriculum vitae with cover letter by **August 24, 2023**. 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”.

Announcement Contact

For questions regarding this Cures position, please contact CDEROC-OUDLC-Recruitment@fda.hhs.gov. Please reference **“Regulatory Counsel vacancy”** in the subject.

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

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