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 Unapproved Drugs and Labeling Compliance (OUDLC)

Application Period: April 10, 2024, - May 15, 2024

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: Deputy Office Director (Supervisory Regulatory Counsel)

Series: AD-0301

Location(s): Silver Spring, MD

Salary: Starting at $181,551

Work Schedule: Full-Time

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: 25% or less

Bargaining Unit: 8888

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 CDER 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 Compliance strives to be a model of efficiency, innovation, and organizational excellence. CDER Compliance makes strategic and risk-based decisions that are guided by law and science to communicate clearly with stakeholders, foster global collaboration, promote voluntary compliance, and take 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.

Duties/Responsibilities

As the **Deputy Office Directory (Supervisory Regulatory Counsel),** the incumbent shares responsibility with the Office Director in managing and directing the development and implementation of the Agency's human unapproved drug and enforcement programs; advises the Office Director, Super Office Director and other senior Agency officials on compliance matters of major significance pertaining to unapproved prescription drugs, over-the-counter drugs, fraudulent drugs, as well as drug registration and listing. Shares responsibility in providing leadership to subordinates and oversight of operations; leads engagement with stakeholders; develops short/long term goals, policy, guidance, and innovative compliance strategies; and leads efforts to achieve strategic objectives and goals.

- Develops and implements policies, surveillance activities, compliance strategies, regulatory actions, and enforcement actions associated with new drug and labeling requirements of the Federal Food, Drug and Cosmetic Act.
- Oversees medical and regulatory experts involved in the evaluation and support of FDA actions pertaining to unapproved drugs and labeling, including foundational evaluations of regulatory status and prescription drug determinations, medical evaluations, declarations, and testimony in support of civil and criminal enforcement cases, as well as regulatory and compliance matters pertaining to medical gas and Positron Emission Tomography (PET) drugs.
- Develops comprehensive policy and procedural guidelines for handling compliance and enforcement actions related to human unapproved drugs. Reviews and approves legal actions in cases where authority has not been delegated to the field, where guidelines have not yet been established, and cases of national scope requiring headquarters coordination.
- Represents the Office Director in meetings on compliance matters of major significance involving unapproved drugs. Represents the Center on behalf of the Office Director in meetings with top level representatives of other Federal and State agencies to obtain

their cooperation on compliance matters of mutual interest. Engages with stakeholders, including top level leaders of regulated industries to promote compliance.
- Formulates and executes plans and budgets for the Office. Continually evaluates budget, fiscal, and administrative controls to manage Office programs and services. Spearheads effective and efficient budget execution.

Supervisory Responsibilities:

- Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate staff (including supervisors and team leads if appropriate) performing the work and functions of the organizational unit.
- Shares responsibility with the Office Director in managing several multi-disciplinary programs, providing leadership and management oversight to a component Office of approximately 50 employees, including scientific, legal, professional, technical, administrative, and clerical personnel ranging in grade from supervisory positions to entry levels.
- Directly supervises two employees in the Immediate Office.

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:

Education: A law degree, specifically a LL.M. or J.D. The degree must be from an accredited program or institution.

OR

Experience: Comparable regulatory experience focused on interpreting laws, rules, regulations, or policies; or develop or analyze regulations and policies for regulated products.

Desired Professional Experience:

Our ideal candidate will possess:

- Ability to apply knowledge of the laws applicable to the Agency's mission, Federal law governing or affecting the unapproved drugs program, federal regulations, and significant national developments in the field.
- Ability to apply knowledge of 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 Federal statutes and regulations or related background.
- Ability to meet and interact, on behalf of the Center, with those persons and organizations having business with or who are influenced by Center programs or related background.
- Ability to manage organizations with regulatory and/or compliance mission(s)
- Demonstrated experience managing the work of a diverse staff to include ensuring desired results, leading people, building coalitions, and collaborating across boundaries to achieve a common goal.

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 Recognition of Foreign Qualifications | International Affairs Office (ed.gov)

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: 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 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 **May 15, 2024, to** CDEROC-OUDLC-Recruitment@fda.hhs.gov.

Please include **Position /Office/Application Period** in the Subject line of the email (*i.e., CURES Supervisory Regulatory Counsel Band F/Office of Compliance/Office of Unapproved Drugs and Labeling Compliance/Application Period 04/08/24 – 04/26/24)* and provide this information in your cover letter.

Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research 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 CDER OC PMAS at CDEROC-OUDLC-Recruitment@fda.hhs.gov

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