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 Regulatory Policy (ORP)
Division of Disclosure Policy (DIDP)

Application Period: October 1, 2024 – October 31, 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: Regulatory Counsel

Series: AD-0301

Location(s): Remote Anywhere in the U.S.

Salary:
$99,200 - $155,859 (Band B)

Work Schedule: Full-Time

Cures Band(s): Band B

Full Performance Band Level: Band C

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 Regulatory Policy (ORP) is to provide Center oversight and leadership in the development of regulations, policies, procedures, and guidance's that affect the drug approval process, and in the development of new legislation. Also, ORP manages the disclosure of official records and information under the Freedom of Information Act, Privacy Act, other statutes, and Food and Drug Administration's public disclosure regulations.

The mission for the Division of Disclosure Policy (DIDP) is to provide Center oversight and leadership in the disclosure of official records and information under the Freedom of Information Act, Privacy Act, other statutes, and FDA's public disclosure regulations.

Duties/Responsibilities

As a **Regulatory Counsel** in the Division of Disclosure Policy (DIDP) within the Office of Regulatory Policy (ORP), the incumbent will be responsible for providing analyses and advice on the interpretation of laws, regulations, and policies and guidance applicable for FDA regulated products. Participate or provide leadership in the development, implementation, and evaluation of regulations and policies as they relate to the Agency's programs and activities to ensure the safety, efficacy, and quality of FDA regulated products.

Band B:

- Performs a legal review of CDER records to determine whether, before being made available for public disclosure, they should be redacted, in part or in their entirety, under applicable Freedom of Information Act exemption, other statutory provision, or, in the context of third-party subpoenas, any applicable privilege in the Federal Rules of Civil Procedure. Assists in the development, implementation, management, and coordination of CDER's disclosure activities.
- Drafts responses to requests for the disclosure of information, including requests under the Freedom of Information Act, by analyzing the request, directing an appropriate search, obtaining the responsive documents, performing a legal review to determine if information is exempt from disclosure, redacting information that is exempt from disclosure, preparing a letter that provides the documents and explains what information is being withheld from disclosure, and obtaining necessary clearances for releasing the records. With regard to litigation-related requests for documents, analyzes the requests; reviews any applicable court orders or settlement agreements regarding document production, directs appropriate searches; determines the applicable statutory exemptions or litigation privileges to apply to disclosure determinations; compiles, indexes, and redacts documents; and assists representatives from the Office of Chief Counsel in the preparation of the rationale for withholding

information.

- Assists in the preparation of Center recommendations for denials of requested information that is exempt from disclosure. Such recommendations include sufficient legal justification and all available evidence to support the recommendation.
- Works with Center and FDA components, including other Centers and the Office of Chief Counsel, on important and sensitive issues regarding information disclosure. Informs the Director of DIDP of all sensitive requests for information, discusses the issues with the Director, and obtains approval for the response and other related actions.
- Reviews Center responses to requests for information. Ensures that requests for information are satisfied in a timely manner and by careful evaluation that all such responses are accurate and contain only information considered disclosable as provided under the Freedom of Information Act, the Privacy Act, the Federal Food, Drug, and Cosmetic (FD&C) Act, and the Department's and FDA's implementing regulations.
- Keeps abreast of current developments in the Center to correctly handle and process disclosure inquiries. The incumbent must have sensitivity to emerging problems that are reflected in disclosure inquiries and must develop legally supportable recommendations for Center action to address the problems. These recommendations are directed to the affected units, within the Center, through the Director of DIDP. The Incumbent ensures appropriate consideration and resolution of such problems.
- Provides guidance and direction to Center personnel involved with handling responses to requests for information and other disclosure activities. This requires an understanding of the Freedom of Information Act, the Privacy Act, pertinent sections of the Federal Food, Drug, and Cosmetic (FD&C) Act, and the Departments and Agency's implementing regulations and policies. Keeps abreast of all changes to the statutes and regulations to ensure Center compliance at all times.
- Due to the importance and sensitivity of the duties performed by the incumbent, Center professional staff are instructed to give the necessary priority attention to requests for information assigned by the incumbent. The timely nature of these matters requires the incumbent to discuss issues with Center professional staff (e.g., Division Directors, consumer safety officers, medical and scientific personnel).

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 is required.
- Financial Disclosure is required.
- Ethics Clearance is required.
- Background Investigation/Security Clearance is required.

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:

Degree: 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 Skills, Experience, or Education:
Our ideal candidate will possess:

- Knowledge of regulatory programs, practices, policies, and procedures is desired, but not required.
- Knowledge of the Freedom of Information Act, the Privacy Act, the Trade Secrets Act, or similar laws at the federal or state level related to the protection of confidential information, is desired, but not required.
- Ability to organize time effectively, determine priorities, and move work forward.
- Ability to communicate orally and in writing and work with staff at all levels of the organization.
- Ability to communicate verbally and in writing with government officials and private citizens.
- Knowledge of pertinent regulatory information in Agency manuals, reference systems, directives, issuances, precedent decisions, court decisions, and commercial publications or similar background information is desired, but not required.

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-Sensitive/Moderate Risk

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 the 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 actions.

Ethics Clearance Requirements

This position requires 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 **October 31, 2024**, to: CDER-ORP-Cures-Hiring@fda.hhs.gov. On the subject line, please reference "**Regulatory Counsel Band B"**. Candidate resumes may be shared with hiring officials within CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share".

How I Will Be Evaluated

Candidates may be evaluated based on an interview, review of requested work samples, writing samples, most recent performance evaluation(s), professional references, results of an oral presentation or work-related test. Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Announcement Contact

For questions regarding this Cures position, please contact CDER-ORP-Cures-Hiring@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.