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 Regulatory Policy I-IV (DRP)

Application Period: June 21, 2024, – July 22, 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): Silver Spring, MD

Salary: Starting at $139,395

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, and radiation emitting devices are safe and effective.

The mission of FDA's Center for Drug Evaluation and Research (CDER) is to ensure 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) and Divisions of Regulatory Policy I-IV is to provide oversight to CDER and leadership in the development of regulations, policies, procedures, and guidances that affect the drug approval process, and in the development of new legislation. ORP is also responsible for responding to a variety of citizen petitions raising complex issues related to regulation of prescription and nonprescription drugs under the Federal Food, Drug and Cosmetic (FD&C) Act and its implementing regulations.

Duties/Responsibilities

As a **Regulatory Counsel** in the Divisions of Regulatory Policy (DRP) I-IV within the Office of Regulatory Policy (ORP), the incumbent is responsible for writing regulations, preparing responses to citizen petitions; drafting and commenting on legislation; and providing advice on the interpretations of the laws, regulations, and policies applicable to the FDA.

- Conducts sophisticated analyses of complex regulatory and policy issues and provides advice to CDER staff relating to the issuance of FDA regulations and petition responses.
- Provides technical advice and guidance to more junior Regulatory Counsels.
- Works on complex and difficult assignments of national scope and significance. Assumes responsibility for ensuring that regulations and policies developed in the assigned areas are consistent with statutory requirements and existing policy, are justified, and supported by appropriate analysis including scientific and medical analyses when required.
- Performs duties that include resolving a broad range of issues concerning the application of any of FDA's enabling statutes, pertinent regulations, and/or general laws affecting the operation of the federal government. Assignments often involve research on complex or controversial regulatory and policy issues of wide public interest and revision of existing policies and regulations or development of innovative policies and regulations.
- Leads working groups of scientific regulatory and experts to develop new or revised regulations and drafts the resulting notices of proposed rulemaking.
- Uses resources such as Westlaw, LexisNexis, Medi Regs, the US Code, the Code of Federal Regulations, the Federal Register, and others, to conduct research regarding established precedents in order to develop and support legally sufficient regulations, citizen petition responses, and policies.

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.

In order 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:

- At least five years of experience in handling regulatory issues (i.e., in a firm, regulated industry or government setting) such as by writing or commenting on regulations; preparing or responding to petitions.
- Drafting or commenting on legislation; or providing advice on the interpretations of laws, regulations, and policies.
- Demonstrated experience and knowledge of federal regulatory programs and FDCA or drug regulatory program experience is highly desired.
- Demonstrated experience and ability to identify and analyze problems; weighing the relevance and accuracy of information; generating and evaluating alternative solutions; and making recommendations.
- Experience and knowledge in regulatory practices, policies, and procedures is highly desired.
- Ability to organize time effectively, determine priorities, and move work forward.
- Ability to work independently and as a contributing, collaborative team member.
- Ability to communicate orally and in writing and work with staff at all levels of the organization and varying levels of domain expertise.
- Demonstrated experience and skill to collaborate across boundaries to build strategic relationships and to achieve common goals.

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 action.

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 **July 22, 2024**, to: CDER-ORP-Cures-Hiring@fda.hhs.gov. 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".

Please reference "**Regulatory Counsel Band D**" in the email subject line.

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.