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 New Drugs (OND)
Office of Therapeutic Biologics and Biosimilars (OTBB)
Policy Staff (PS)

Application Period: December 9, 2024 - December 23, 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

Work Schedule: Full-Time

Salary: Starting at $139,395

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: 3591

Relocation Expenses Reimbursement: You WILL NOT 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 Office of New Drugs (OND) is a super office within CDER responsible for the assessment of new drugs and therapeutic biologics. OND provides clinical, nonclinical, and regulatory expertise on the full range of drugs and therapeutic biologics that can be made available to the American people.

The Office of Therapeutic Biologics and Biosimilars (OTBB) coordinates and supports all biosimilar and interchangeable product activities in the Center for Drug Evaluation and Research (CDER). OTBB is the central point of contact for CDER staff for biosimilars, therapeutic biologics, and follow-on versions of complex protein products and other complex products.

The Policy Staff (PS) provides technical assistance and regulatory policy development efforts pertaining to biosimilar and interchangeable biological products. Key workstreams include briefing material development and presentation; inquiry responses; proposed legislation, rules, and regulations; guidance and other policy documents; product- and application- specific policy issue work.

Duties/Responsibilities

As a **Regulatory Counsel**, the incumbent is recognized as the authority in one or more program segments, functions, and activities concerning OTBB policies and is the expert that is called upon to develop and communicate definitively those policies internally as well as to external stakeholders. The incumbent is responsible for regulatory and policy-related activities including planning, reviewing, and evaluating the policy development and implementation work of the Office.

- Serves as an advisor and spokesperson in matters related to regulatory policy and procedures, and other complex areas that affect the Office's mission-critical programs and activities.
- Leads, initiates, coordinates, monitors, and/or reviews the development and implementation of regulatory policies, standards, and procedures (including rulemaking initiatives, industry guidance, and internal agency procedures and policies) concerning the regulatory activities of the OTBB.
- Advises senior Center and Agency officials and others on regulatory and policymaking

activities that affect a wide variety of legal and regulatory programs, projects, and initiatives impacting the OTBB.
- Works in regulatory policy development and implementation in OTBB, OND, and CDER, including when such projects affect multiple offices in CDER or multiple product centers in FDA.
- Provides strategic advice to the PS and OTBB leadership in formulating, developing goals and advancing programs and upholding FDA's public health responsibilities.
- Develops novel Agency positions in collaboration with OTBB leadership on a variety of issues in response to requests for advisory opinions from the regulated industry, Congress, Department officials, as well as others.
- Maintains current knowledge about new legislation, new or revised regulations, new or revised guidance, internal policies and procedures and trends in the pharmaceutical and health care industries and informs senior leadership and staff of new information that is important to OTBB's mission.

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.

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 Requirements:

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 Education, Experience, Professional Experience:
Our ideal candidate will possess:

- Relevant recent experiences in statutes, regulations, guidance, and precedents which relate to the activities of government organizations.
- Demonstrated skills in reviewing policy documents and decision memoranda to ensure that they are comprehensive, accurate, and consistent with the Administration and Department policy.
- Experience in identifying, articulating, addressing, and resolving unique, far-reaching and/or previously unresolved problems and complex issues.
- Mastery professional knowledge of the various titles of law applicable to the Agency's mission, Federal laws governing or affecting FDA regulation of drugs and biological products, and Federal regulations.
- Skill in communicating and negotiating with diverse scientific, legal, and management professionals on a wide range of issues related to drugs and biological products.
- Skill in providing expert advice and guidance on the regulatory program segments, functions, and activities that include providing advice and guidance to industry representatives or Federal program managers.
- Ability in analyzing, evaluating, and interpreting complex Federal statutes and

regulations or related background and ability to draft complex, legal documents such as correspondence, briefs, legal opinions, legal memoranda, and press releases related to regulatory requirements.
- Ability to write technically sound documents such as issue papers, memoranda, report summaries with analyses and recommendations.

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 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 and unofficial transcripts by **December 23, 2024,** to Preslie Fisher at ONDIORecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring officials within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference **Job Reference ID: BB-24-023** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact OND IO Recruitment Team at ONDIORecruitment@fda.hhs.gov.

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