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 Generic Drugs (OGD)
Office of Generic Drug Policy (OGDP)
Division of Legal & Regulatory Support (DLRS)
Division of Policy Development (DPD)

Application Period: December 20, 2023- January 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): Silver Spring, MD

Salary: Starting at $132,368

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: Relocation expenses will not be paid.

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 Generic Drugs (OGD) is to ensure high-quality, affordable generic drugs are available to the American public. OGD is the world leader in the science and regulation of generic drugs, serving an essential role in advancing FDA's public health mission.

The Office of Generic Drug Policy (OGDP) serves as the Agency's lead on generic drug policy and regulation to enable generic drug approvals and provide the public with high quality, affordable medicines. We achieve this by advocating on behalf of the generic drug program and providing counsel in a complex, ever-changing legal and regulatory environment.

The Division of Legal and Regulatory Support (DLRS) mission is to advise the Office of Generic Drugs on generic drug application specific legal regulatory and policy issues in the course of FDA implementation of Section 505(j) of the Federal Food, Drug, and Cosmetic Act. The Division is responsible for providing expertise on generic drug regulatory issues at both the Center and Agency level.

The Division of Policy Development (DPD) mission is to provide strategic leadership and direction in the development, clearance, and implementation of regulations, guidance, policies, procedures, and other documents affecting the regulation of generic drug products. The Division collaborates with all FDA offices supporting the generic drug program to ensure timely implementation and fulfillment of FDA's commitments pursuant to the Generic Drug User Fee Amendments (GDUFA).

Duties/Responsibilities

As **Regulatory Counsel**, the incumbent assumes primary responsibility for ensuring that regulations and policies developed in the assigned area are consistent with statutory requirements and existing policy; that their need is justified, and that scientific and regulatory decisions have been appropriately documented. The Regulatory Counsel handles highly complex and difficult assignments of national scope and significance.

- Reviews petitions raising issues that have an effect on the generic industry as well as those that pertain to the marketing status of generic products. Develops a course of action for the Office response to these petitions.
- Prepares replies to correspondence from the regulated industry and other interested persons on issues that are industrywide in scope or have broad health-policy implications and that concern precedent setting interpretations of FDA policy.
- Develops petition responses, regulatory documents, and other written statements of Agency policy, consults with staff at all levels of the Agency to identify areas of disagreements between components, resolve disagreements using decisional

memoranda or meetings, and articulate any policy consensus reached through this process.
- Manages and resolves a broad range of issues concerning the implementation of FDA's enabling statutes, including those related to generic drug regulation and the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, pertinent regulations, guidance documents, standard operating procedures, and other policy documents related to the regulation of generic drug products.
- Coordinates and manages special projects as assigned and advises others concerning FDA statutes and regulations pertaining to generic drugs.
- Researches and resolves regulatory issues related to information that is published in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

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:

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

Desired Professional Experience:
Our ideal candidate will possess:

- Knowledge of federal regulatory programs is required; knowledge of drug law is desired, and significant experience in leading employees and functioning at the managerial level is desired.
- Possession of significant knowledge of regulatory practice, policies, and procedures, with experience related to the Hatch-Waxman Amendments and the generic drug program is highly desired.
- Demonstrated ability to identify and analyze problems; weigh the relevance and accuracy of information; generate and evaluate alternative solutions; and make recommendations.
- Expert ability to communicate and work with staff at all levels of the organization and varying levels of domain expertise; demonstrated ability to collaborate across boundaries to build strategic relationships and achieve common goals.
- Ability to work independently and as a contributing, collaborative team member.
- Ability to organize time effectively, determine priorities, and move work forward.

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/High 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 as a single document file by **January 31, 2024,** to: OGDPPMASTeam@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”.

Announcement Contact

For questions regarding this Cures position, please contact OGDPPMASTeam@fda.hhs.gov.

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

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