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 Drug Security, Integrity, and Response (ODSIR)

Application Period: 3/15/2021 – 3/26/2021
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-301

Location(s): White Oak, Silver Spring, MD

Salary: Starting at $121,316

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

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 compensated 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 are 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 (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The mission of the CDER Office of Compliance (CDER OC) is to shield patients from poor quality,

unsafe and ineffective drugs through proactive compliance strategies and risk based enforcement actions. CDER OC strives to be a model of efficiency, innovation and operational excellence. Guided by law and science, CDER OC makes strategic and risk-based decisions, communicates clearly with all stakeholders, fosters global collaboration, promotes voluntary compliance and takes decisive action.

As the **Regulatory Counsel** in the Office of Drug Security, Integrity, and Response (ODSIR) Division, Global Drugs Distribution and Policy (DGDDP) and Supply Chain Integrity (DSCI), the incumbent serves as an expert in the statutes, regulations, policies, procedures, and implications relevant to the issuance of FDA regulations, conducts sophisticated analyses of complex regulatory and policy issues for the CDER imports and recalls program areas and leads policy development activities. Provides advice to staff in CDER in carrying out its regulatory mission.

Duties/Responsibilities

- Develops policies and programs involving complex and high priority matters affecting the regulation of drug products. Drafts or critically reviews documents embodying policy and program proposals and decisions on these products, including proposed legislation and policy statements. These regulations and policy statements often result from the need to implement new legislation or from new interpretations of existing laws. They may be broad in scope and affect either an entire or a significant sector of a regulated industry.
- Uses resources such as Westlaw, LexisNexis, MediRegs, the US Code, Code of Federal Regulations, the Federal Register, and others, to conduct research regarding established precedents in order to develop and support legally sufficient regulations and policies.
- Leads working groups of scientific, regulatory and legal experts to develop new or revised regulations and drafts the resulting notices of proposed rulemaking.
- Reviewsand draft responses to public comments received on proposed regulations, recommends adoption or rejection of counter-proposals contained in the resulting comments and objections, and drafts final regulations.
- Prepares replies to correspondence from the regulated community, Congress, and other interested stakeholders on issues that are industry-wide in scope or have broad health implications and that concern precedent-setting interpretations of laws governing FDA and FDA's policy.
- Drafts and comment on proposed legislation on matters pertaining to FDA's jurisdiction.
- Reviews and comment on legal pleadings in litigation involving FDA such as affidavits, briefs, motions for summary judgment and dismissal, when requested to do so by the FDA Office of Chief Counsel.
- Advises other offices in the Center on procedures and methods for implementing new regulations and revising existing regulations and on the sufficiency and procedural adequacy of proposed policy statements and policy initiatives.
- Provides guidance and/or training to regulatory specialists and other professionals within FDA on matters relating to his/her expertise.

- Advises staff in the Office of Chief Counsel and other offices within the Office of Commissioner on matters related to the Regulatory Counsel's responsibilities.
- Develop regulations and other written statements of agency policy, consults with staff at all levels of the Agency, including the Commissioner, to identify areas of disagreement within the Center or between the Center and other units of FDA to resolve disagreements through the use of decision memoranda or meetings, and to articulate any policy consensus reached through this process.

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 Requirement: A juris doctorate degree from an accredited institution of higher learning.

Desired Education: N/A

Professional Experience:

- Master of occupational specialty. Skilled in applying knowledge to all occupation-related duties and responsibilities.

- Expert knowledge of the various titles of law applicable to the Agency's mission, Federal law governing or affecting the program, Federal regulations, and significant national developments in the field. These laws may include, but are not limited to, the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act or related types of legislation.

- Mastery of other 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 complex Federal statutes and regulations or related background. Ability to meet and deal effectively on behalf of the Center with those persons and organizations having business with or who are influenced by Center programs or related background.

Desired Professional Experience: N/A

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-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 **3/26/2021** to: **CDER-OC-ODSIR-Recruitment@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". For questions please contact CDER-OC-ODSIR-Recruitment@fda.hhs.gov. Please reference Job Reference ID: T-21-394-D

Announcement Contact

For questions regarding this Cures position, please contact CDER-OC-ODSIR-Recruitment@fda.hhs.gov.

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