



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 Generic Drugs (OGD)
Office of Generic Drug Policy (OGDP)
Division of Legal and Regulatory Support (DLRS)

Application Period: December 20, 2021-January 18, 2022

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): Silver Spring, MD

Salary: Starting at \$122,530

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

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 or Agency) 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 Office of Generic Drugs (OGD) and its sub offices 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 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. OGDP's **Division of Legal and Regulatory Support (DLRS)** advises OGD regarding generic drug application-specific legal, regulatory, and policy issues and serves as agency experts on Hatch-Waxman and other generic drug regulatory issues. DLRS also tracks and helps expedite review of public health priority submissions, including for first generics and drug shortages, to help achieve timely approval of generic drug products, and advises and makes decisions on patent and exclusivity matters for brand and generic drugs and determines timing of generic drug approval.

Duties/Responsibilities

- Develops policies and programs involving the most complex and highest priority matters affecting the regulation of generic drug products. Drafts or critically reviews documents embodying policy and program proposals and decisions on these products. These documents state or interpret Center or FDA policy for the regulated industry and other affected groups and receive minimal review before transmittal to management or other stakeholders.
- Reviews policy and other regulatory documents drafted by other offices that impact generic drug regulation. Drafts revisions and technical corrections to new and existing regulatory documents.
- Serves as an expert consultant on the generic drug regulatory review process within FDA and to other interested groups.
- Reviews petitions raising issues that have an effect on the generic industry and FDA's regulation of generic drug products. Leads and coordinates the Office consult response to, and clearance of, these petitions.
- Prepares responses to correspondence from the regulated industry and other interested persons on issues that are industry-wide in scope or have broad health-policy implications and that concern precedent-setting interpretations of FDA policy.
- In developing 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.

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:

There are no Individual Occupational Requirements for this series.

Desired Education:

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

Professional Experience:

- Knowledge of federal regulatory programs is required; knowledge of drug law is desired.
- Significant experience leading projects independently with minimal supervision 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 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.

Desired Professional Experience:

5 years in an attorney or regulatory professional role providing advice on federal regulatory issues. Experience practicing food and drug law in a law firm, government agency, or in-house in the pharmaceutical industry is highly desired.

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:

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 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 by January 18, 2022 to: Lauren.Sams@fda.hhs.gov. Candidate resumes may be shared with hiring official 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 Lauren.Sams@fda.hhs.gov.

Announcement Contact

For questions regarding this Cures position, please contact Lauren.Sams@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.

