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)

Application Period: January 9, 2023 – January 30, 2023

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: Division Director (Supervisory Regulatory Counsel)

Series: AD-0301

Location(s): Silver Spring, Maryland

Salary:
Starting at: $168,964
Band maximum: $266,934

Work Schedule: Full Time

Full Performance Band Level: Band F

Cures Band(s): Band F

Travel Requirements: Up to 25%

Bargaining Unit: 8888

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 Office of Generic Drugs (OGD)'s mission 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. OGDP provides oversight and direction in the development and implementation of regulations, guidance, and other policy statements concerning generic drugs, and advises the generic drug program on application-specific regulatory and policy issues relating to the generic drug review process and other Hatch-Waxman regulatory matters, including those related to patents and exclusivities.

OGDP's Division of Legal and Regulatory Support (DLRS) advises OGD on generic drug application specific legal, regulatory, and policy issues and provides expertise on generic drug regulatory issues at both the Center and Agency level.

The Division Director position is in OGD's Office of Generic Drug Policy, Division of Legal and Regulatory Support.

Duties/Responsibilities

As the **Division Director**, the incumbent serves as principal advisor to the OGDP Office Director and Deputy Office Director on decision-making processes and documents and participates fully in discussions and decisions concerning DLRS and OGDP plans, programs, and activities in both strategic planning and in the actual determination, allocation, and administration of CDER program segments, functions, and activities.

- Advises Office Director and division staff on complex, long-range, and emerging conflicts in the regulatory field as applied to the work products related to generic drug regulation for which the staff is responsible, including the Hatch-Waxman Amendments. Keeps fully abreast of crucial and precedent-setting issues, regulatory policy interpretations, and analyses under review within the FDA, Center, Office, and Division, and as such issues arise in regulated industry.
- Leads and manages a division to function as liaison to and support the work of CDER and FDA organizations, including the FDA Office of Chief Counsel and CDER's Office of Regulatory Policy, with respect to generic drug matters. Advises on matters concerning FDA statues and regulations pertaining to generic drugs; and resolves complex, controversial, and unusual matters of major consequence or importance to the Agency.
- Oversees the following processes: adjudicating and drafting responses to suitability

petitions, consults for and review of citizen petition responses, and administrative record preparation in support of certain regulatory actions. Provides support for ongoing litigation involving OGD matters. Reviews all generic drug applications prior to approval to determine eligibility for final or tentative approval based on the patent and exclusivity landscape and the complex timing-of-approval provisions of the Hatch-Waxman Amendments. Coordinates OGD's response to drug shortages and compiling and reporting on certain information related to generic drugs, including statutorily required reports to Congress.

- Manages the process for the development of petition responses, regulatory documents, and other written statements on Agency policy that are often industry-wide in scope or have broad health- policy implications that concern precedent-setting interpretations of FDA policy. Ensures that subordinate Regulatory Counsels and other staff have consulted with staff at all levels of the Agency to identify areas of discrepancy between the scientific or regulatory positions of disciplines within OGD and/or CDER, and that such disagreements are resolved.
- Represents DLRS and OGDP in engagements with organization such as Congress, other Federal agencies (i.e., Department of Justice, Federal Trade Commission, Patent and Trademark Office, Centers for Medicare and Medicaid Services, and the Department of Defense), State, local, and foreign governments, the regulated industry, professional and industry organizations, and public interest groups to provide subject matter expertise, communicate OGDP's position on generic drug regulatory matters, educate on generic drug regulation, and advocate on behalf of the program.

Supervisory Responsibilities: Manages a regulatory program, providing leadership and management oversight to subordinate staff at least 25% of the time.

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

There are no Individual Occupational Requirements for this series. For more information, please see: OPM Occupational Series Qualification Requirements.

Desired Education:

Our ideal candidate will possess: A juris doctorate degree from an accredited institution of higher learning.

Desired Professional Experience:

Our ideal candidate will possess:

- Ability to apply, analyze, and interpret knowledge of federal regulatory programs and administrative law including experience applying the Food, Drug, and Cosmetic (FD&C) Act to drug regulatory activities.
- Demonstrated experience in leading employees and performing at the managerial level is desired.
- Experience utilizing advanced collaboration skills to drive collaboration, empower staff, and is committed to the Public Health mission.
- Expert ability to communicate orally and in writing with staff at all levels of the organization and varying levels of domain expertise.
- Demonstrated ability to identify and analyze problems; weigh the relevance and accuracy of information; generate and evaluate alternative solutions; and make recommendations.

- Demonstrated ability to collaborate across boundaries to develop networks, build strategic alliances, 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.

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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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

How to Apply: Submit resume or curriculum vitae with cover letter as a single document file by **January 30, 2023,** to: OGDPPMASTeam@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 the OGDP

PMAS Team at OGDPPMASTeam@fda.hhs.gov.

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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