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: November 21, 2022- January 6, 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: Super Office Director, OGD

Series: AD-0602/0601/1320/0405/0415

Location(s): Silver Spring, MD

Salary: Starting at:
$247,369 (AD-0601,1320,0405,0415)
$250,000 (AD-0602)
*Starting salary is minimum of band and may be set higher, commensurate with education/training and experience.

Work Schedule: Full Time

Cures Band(s): Band H

Full Performance Band Level: Band H

Travel Requirements: 25% or less

Bargaining Unit: 8888

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 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 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, effective, and quality 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 Office of Generic Drugs (OGD) ensures high-quality, affordable generic drugs are available to the American public by overseeing the development and implementation of standards for the safety and effectiveness of generic drugs.

The mission of the Immediate Office (IO) provides oversight, leadership, strategic direction, and support for the Office of Generic Drugs (OGD) and its five sub-offices: Office of Bioequivalence, Office of Generic Drug Policy, Office of Regulatory Operations, Office of Research and Standards, and Office of Safety and Clinical Evaluation.

Duties/Responsibilities

As the **Director** of the Office of Generic Drugs (OGD), the incumbent is responsible for directing OGD activities which include developing and implementing standards for the safety, effectiveness, and quality of generic drugs, reviewing, and evaluating Abbreviated New Drug Applications (ANDAs) and their amendments or supplements to determine approvability, establishing bioequivalence specifications for drug products, including overseeing a regulatory science program to inform these activities, and developing guidelines for bioequivalence reviews, industry protocols, and studies. Responsibilities also include implementation of the Generic Drug User Fee Act (GDUFA) as well as communicating with internal and external stakeholders.

Serves as the principal medical and technical authority on all matters related to the review of generic drugs and as the scientific advisor to the Center Director and other essential Center and agency officials. In addition to the OGD Immediate Office (IO), the incumbent provides leadership and direction to the five sub-offices within OGD: 1) Office of Research and Standards; 2) Office of Bioequivalence; 3) Office of Generic Drug Policy; 4) Office of Regulatory Operations, and 5) the Office of Safety and Clinical Evaluation (OSCE).

Provides expert scientific/clinical support and advice to the Center on developing regulatory standards for the bioequivalence and safety of generic drugs, including:

- Directing and coordinating the medical and related professional activities in overseeing and monitoring the development and implementation of regulatory standards for the therapeutic efficacy and safety of generic drugs
- Overseeing the reviews and evaluation of ANDAs and their amendments or supplements and determining approvability
- Developing, establishing, and implementing standards for the safety and effectiveness of generic drugs
- Establishing and enforcing safeguards for the testing of generic drugs in humans

- Applying expert medical and scientific standards of approval that ensure generic versions substitutability and therapeutic equivalence to brand-named products s
- Providing fair and equitable processing of ANDA amendments, supplements, and other regulatory submissions, to ensure equal competitive opportunities among generic drug sponsors
- Maintaining a thorough knowledge and understanding of the pre-and-post-market evaluation of generic drugs for safety and equivalence
- Provides consultation and expert advice on generic drug standards to FDA's Office of the Commissioner, FDA Centers, other government agencies, foreign governments, and domestic and international organizations.
- Serves as a scientific advisor and consultant to the Center Director and higher-level Agency officials on the functions and programs that are the responsibility of the office.
- Represents FDA at professional meetings, committees, and working groups, as well as prepare and present testimony to Congress.

Supervisory Responsibilities: Manages one or more portfolios and provides leadership and direction for multiple, smaller program offices.

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 *supervisory* 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:
General Health Science Series, AD-0601
Chemistry Series, AD-1320
Pharmacology Series, AD-0405
Toxicology Series, AD-0415
Physician Series, AD-0602

For more information, please see: OPM Occupational Series Qualification Requirements.

At a minimum, the candidate must possess a doctoral-level degree from an accredited institution of higher learning, including Ph.D., M.D., D.V.M., D.D.S., D.M.D., Sc.D., or other research doctoral-degree widely recognized in U.S. academia as equivalent to a Ph.D.

Desired Professional Experience:

- Substantial leadership experience including an established track record in drug development and the management of staff.
- Experience formulating and establishing strategies and policy relating to generic drugs.
- Executive level experience in a large, complex organization or function of 50 or more employees.
- Experience collaborating with top level officials within the organization as well as officials from Federal, state, or city governments, professional health organizations, the regulated industry, consumer organizations, advocacy groups, etc. to accomplish goals.
- Demonstrated ability and experience coordinating complex issues and tasks and building coalitions with partners in other organizations.
- Experience with budget formulation.
- Demonstrated experience in overseeing successful recruitment and retention efforts.
- Experience creating a culture and environment that embraces change and is inclusive.
- Ability to apply knowledge of one or more professional fields (e.g., medical field, health filed, allied sciences, physical sciences) and skill sufficient to identify and understand the most difficult, complex, and broad agency regulations and provide executive leadership

and guidance in an area that has a major impact on public health.

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

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.

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

Submit resume or curriculum vitae with cover letter by **January 6, 2023**, to: CDER-OCD-OEP-Hires@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research (CDER) with a similar job vacancy. Candidates can opt out of this

process by annotating resume with “do not share”. For questions, please contact Ashley Corum-Lawson, Supervisory Administrative Officer, Ashley.Corumlawson@fda.hhs.gov. **Please reference Job Reference ID: E-22-953-H.**

Announcement Contact

For questions regarding this Cures position, please contact Ashley.Corumlawson@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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