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 New Drugs (OND)
Office of Immunology and Inflammation (OII)
Division of Rheumatology and Transplant Medicine (DRTM)

Application Period: July 18, 2024 – August 12, 2024

Area of Consideration: CDER-wide. 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: Associate Director for Therapeutic Review (Supervisory Physician)

Series: AD-0602

Location(s): Silver Spring, MD

Salary: Starting at $195,000

Work Schedule: Full-Time

Cures Band(s): Band E

Full Performance Band Level: Band E

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 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 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 Office of New Drugs (OND) is a super office within the Center for Drug Evaluation and Research responsible for the assessment of new drugs and therapeutic biologics. OND provides clinical, nonclinical, and regulatory expertise on the full range of drugs and therapeutic biologics that can be made available to the American people.

The Office of Immunology and Inflammation (OII) reviews Investigational New Drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials. OII evaluates for safety and effectiveness and approves New Drug Applications (NDAs) and Biologic Licensing Applications (BLAs) for products regulated by this Office, specifically products related to dermatology and dentistry, gastroenterology, hepatology and nutrition, pulmonology, allergy, and critical care, rheumatology, and transplant medicine.

The mission for the Division of Rheumatology and Transplant Medicine (DRTM) is to regulate and review Investigational New Drug (IND) applications and marketing applications for drug and biologic products for the treatment of rheumatology and transplant medicine.

Duties/Responsibilities

As the **Associate Director for Therapeutic Review (Supervisory Physician)**, the incumbent is responsible for providing direction and leadership to scientific and clinical review staff involved in the complex task of regulating and evaluating new drugs and biological products. The staff are engaged in the review of human drug trials in the United States, in review of new drug applications (NDAs) and biologics license applications (BLAs) for marketing drugs and therapeutic biologics in this country, and in regulating over the counter (OTC) drug products. This position is a standard position to be used throughout OND Office, Division, Branches, specifically the clinical divisions located within the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER) and belongs to FDA's Physician Job Profile that covers all classes of positions the duties of which are to advise on, administer, supervise, or perform professional and scientific work in one or more fields of medicine.

- Performs tertiary review, makes major decisions, and takes actions which have a direct and substantial effect on the organization, the programs managed, and the American public. Such decisions can be of the most controversial, complex, or critical nature.
- Provides senior supervision and leadership for scientific and regulatory decision¬ making within the division and cross-office input on challenging scientific and regulatory issues. Obtains data and develops information that leads to evidence which supports

regulatory decision making in drug development and formulates decisions or recommendations regarding approvability. Ensures the multi-discipline scientific reviews teams decision adhere to internal review guidance and policies. Serves as chair for industry meetings and has designated signature authority on non-NME, NDAs/BLAs, supplements, IND protocol reviews managed by the division.

- Provides advice and information on drug products under the divisions scope of responsibility to OND internal offices, CDER offices, and Agency with regards to medical and scientific issues, application status, and regulatory actions. Provides supervisory review of scientific reviews, presentations, general advice letters other information request correspondence prepared by subordinate staff for correctness of medical facts and conformance to existing policy.
- Ensures adherence to the appropriate statute, regulatory requirement as well as user fee commitment.
- Collaborates with internal and external stakeholders on surveillance and evaluation of the drug labeling and clinical experience from various sources.
- Represents the Division in meetings/conferences with other Divisions and Office leadership, academia and regulated industry related to issues pertaining to drug development in the designated therapeutic area, safety, and other matters associated with the marketing of drugs and biologics which fall within the purview of the Division; advises other agencies of government to include NIH and CDC as appropriate, industry representatives, and others on medical-scientific questions, including methods and criteria for research and testing, and performance of clinical research.
- Represents FDA on committees or at meetings of scientific and professional groups with both national and international groups and organizations outside the government and with industry; consult with and advises representatives of other government agencies, industry, and the academic community.

Supervisory Responsibilities: Supervises and evaluates staff who serve as experts in their field. Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate supervisors and staff performing the work and functions of the organizational unit. Obtains resources and identifies strategic objectives for the organization.

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.

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:

Physician, AD-0602 Series:

Education: A degree from an accredited program or *institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. *Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates.

AND

Graduate Training: In addition to a degree, a candidate must have had at least one year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internships, residency, and fellowship programs that are approved by accrediting bodies recognized within the US or Canada.

Professional Experience:
Our ideal candidate will possess:

- Knowledge of NDAs, BLAs, supplemental applications for investigational new drug (INDs) requests, OTC drug, and monograph products.
- Ability to drive collaboration, empower staff, provide expert advice and consultation, coordinate program activities, and spearhead important program initiatives.
- Knowledge of leadership principles and concepts regulating and evaluating new drugs and biological products.
- Ability to manage and lead a diverse interdisciplinary staff.

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 Recognition of Foreign Qualifications | International Affairs Office (ed.gov)

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 by **August 12, 2024**, to: CDER-OND-AOS3-Recruit @fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this

process by annotating resume with “do not share”.

Please reference **Job Reference ID**: OND-OII-004

Announcement Contact

For questions regarding this Cures position, please contact Danielle Harris at danielle.harris1@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.