Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of New Drugs (OND)
Office of Non-Prescription Drugs (ONPD)
Division of Non-Prescription Drugs II (DNPDII)

Application Period: January 10, 2022-January 31, 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: Lead Physician
Series: AD-0602
Location(s): White Oak, Silver Spring, Maryland
Salary: Starting at $180,000

Work Schedule: Full Time
Cures Band(s): Band D
Full Performance Band Level: Band D

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 Center for Drug Evaluation and Research (CDER), Office of New Drugs (OND), Office of Nonprescription Drugs (ONPD), Division of Nonprescription Drugs II (DNPDII), located at the Food and Drug Administration (FDA), is conducting a search for talented leaders for the position of **Lead Physician**.

OND is a multi-disciplinary organization engaged in the oversight 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 over the counter (OTC) drug products.

The Office of Nonprescription Drugs (ONPD) serves as the Agency's experts in nonprescription drug development and provides advice and information to other components of CDER, FDA, and other parts of government; maintaining expertise on nonprescription drug products with respect to medical and scientific issues, status of drug and biologics applications, appropriate policy, and proposed regulatory actions affecting nonprescription drug and biologic products.

Duties/Responsibilities

The incumbent serves as a Lead Physician and is responsible for assisting the supervisor with administrative direction and oversight in their assigned clinical division. The Lead Physician ensures that the organization's strategic plan, mission, vision, and values are communicated and integrated into the team's strategies, goals, objectives, and work. In addition, the Lead Physician communicates key milestones to the team, coaches the team in the selection and application of appropriate problem-solving methods and techniques, and leads the team in identifying, distributing, and balancing workload among employees. In these capacities, the incumbent:

- Leads clinical assignments related to the New Drug Applications (NDAs), Biologic License Applications (BLAs), industry-submitted OTC Monograph Order Requests (OMORs), or FDA-initiated OTC Monograph Orders.
- Serves as an authority on the clinical aspects of the drug or biologic applications in his/her therapeutic areas as it relates to marketing approval and enforcing safeguards for testing of investigational drugs and biologics in humans.
- Evaluates the proposed clinical trials for safety, appropriateness of the study population, and other study design items, where the Lead Physician serves as a participant in the evaluation process.
- Determines if human subjects in clinical research of investigational new drugs or biologics can be protected from unreasonable risks.
- Reviews work for completeness of scientific, clinical, and medical content for Investigational New Drug Applications (INDs) for all drugs and biological products regulated by the FDA, and for OTC monograph drug products prior to submission of over-the-counter Monograph Order Requests (pre-OMORs).
- Reviews the proposed product label submitted by the sponsor to ensure its accuracy and that it is supported by the submitted evidence.
- Addresses issues of clinical benefit and risk so that they may be jointly evaluated with biostatisticians and representative of other disciplines with appropriate expertise, documents the findings regarding efficacy and safety which culminates in a benefit-risk assessment after the evaluation, and ensures the benefit-risk assessment is included in the physician's recommendations for whether the application for marketing approval should be approved or rejected.

- Serves as an expert in verbal and written communications with IND sponsors, providing clinical, scientific, and regulatory advice regarding clinical development programs, and incorporating written review of protocol deficiencies to the IND sponsor and clarifications regarding clinical studies, adverse event reports and safety summaries.
- Represents the Agency position on the NDA, BLA, or OMOR at internal and sponsor-attended meetings and at Advisory Committee meetings, presents Agency concerns, questions, or positions at Advisory Committees and other meetings and conferences, and drafts responses to inquiries from Congress, the press, and the public.
- Serves as coach and facilitator in coordinating team initiatives, policy implementation, and consensus building.
- Prepares reports and maintains records of work accomplishments and supporting information, represents the team in dealings with the supervisor and manager to obtain resources and secure information for decisions, and reports to the supervisor on team and individual work accomplishments, problems, and work processes, including individual and team training needs.
- Represents the team consensus and conveys the team's findings, and reports to the team on progress in meeting team milestones and deadlines for completion of assignments.
- Applies a wide range of qualitative and quantitative methods to analyze and improve team effectiveness and leads the team in assessing its strengths and weaknesses.
- Performs other duties as assigned.

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 later.

- THIS POSITION IS SUBJECT TO EXECUTIVE ORDER 14043 MANDATING COVID-19 VACCINATION FOR FEDERAL EMPLOYEES. See section titled Vaccination Requirements for more Conditions of Employment for this position.

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 0602 Series

- Degree: Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent from a school in the United States or Canada. This degree must have been accredited by the Council on Medical Education of the American Medical Association' Association of American Medical Colleges, Liaison Committee on Medical Education, Commission on Osteopathic College Accreditation of the American Osteopathic Association, or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.
- 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, a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination.
- Licensure: Applicants must possess a current active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.
- Residency Training: Minimum of three years residency training or equivalent experience and training.

Professional Experience:

- Skill in applying clinical and scientific expertise to complex multifaceted medical problems such as benefit/risk determinations. Understanding of advanced professional theories, principles, concepts, standards, and methods sufficient to conceive and apply to unique circumstances and develop an understanding of these new circumstances, and to determine appropriate actions.
- Ability to resolve unique or novel problems and conditions, thereby addressing complex and challenging problems in the context of regulatory review of medical products.
- Knowledge of clinical, medical, and scientific literature and current clinical activities relating to new drugs and biologics in the assigned therapeutic area.

Desired Professional Experience:
The ideal candidate will possess:

- Strong interpersonal skills to deal effectively with interdisciplinary teams and diverse stakeholders.
- Strong verbal and written communication skills.
- Skill in applying clinical and scientific expertise to complex multifaceted medical problems such as in benefit/risk determinations.
- Knowledge of clinical trial design and experience in regulatory review of drugs, devices and/or biologic products.
- Working knowledge of FDA regulations, policies, and guidance pertinent to OTC drug development.
- Knowledge of clinical, medical, and scientific literature and current clinical activities relating to new drugs and biologics in the assigned therapeutic area.

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

This position requires a Public Trust security clearance, and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of non-sensitive information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the HHS plan for a Drug Free Workplace.

Vaccination Requirements

As required by Executive Order 14043, Federal executive branch employees are required to be fully vaccinated against COVID-19 regardless of the employee's duty location or work arrangement (e.g., telework, remote work, etc.), subject to such exceptions as required by law. If selected, you will be required to be vaccinated against COVID-19 and submit documentation of proof of vaccination by November 22, 2021 or before appointment or onboarding with the agency (if later than November 22, 2021). The agency will provide additional information regarding which forms of documentation can be accepted and how you can request a legally required exception from this requirement.

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 to ONDIORecruitment@fda.hhs.gov by no later than January 31, 2022. 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: B-21-240**.

Announcement Contact

For questions regarding this Cures position, please contact Natasha Townsend, Natasha.Townsend@fda.hhs.gov.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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