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 Neuroscience (ON)
Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP)

Position: Physician (Pain Medicine)

Pay Plan-Series: 0602, Physician

Location(s): Silver Spring, MD

Travel Requirements: 25%

Application Period: 4/22/2020 – 6/21/2020 (60 days)

Salary: Starting at $165,000 (Cures Band C)

Area of Consideration: United States Citizens or Nationals

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

Special Notes: This position is being filled under an excepted 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 the authority.

Additional information on 21st Century Cures Act can be found here.

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 and prescription drugs, including biological therapeutics and generic drugs.

The Office of New Drugs' (OND) public health mission is to protect and enhance the health of the public through the review and evaluation of scientific data submitted by pharmaceutical manufactures in support of New Drug and Investigational New Drug applications (NDA/IND), and to determine if candidate drugs are safe and effective.

Position Summary:

As a Physician (Pain Medicine), the incumbent will be responsible for providing regulatory oversight for investigation studies during drug development and making decisions regarding marketing approval for new (innovative or non-generic) drugs, including decisions related to changes to already marketed products; monitoring the post market safety and effectiveness of medical drug products marked and used nationwide; advise on policy guidance, documenting review and interpretations of legislation affecting new drugs; establishing policies regarding the analysis and interpretation of surveillance or regulation of new drugs, generic or over-the-counter (OTC) drugs; providing guidance on safe and effective drug issues; determining the safety or efficacy of consumer drugs in clinical settings; and serving as the technical expert on medical drug product issues to the FDA and external organizations within the private and public sectors.

Supervisory responsibilities: N/A

Duties/Responsibilities:

Serves as a Physician (Pain Medicine) determining whether clinical trials of new drugs in humans are soundly conceived, and supported by prior animal testing and other controls adequate to justify tests in humans review applications by manufacturers for permission to market new drugs for general use; applications should be approved based on an evaluation of the evidence of their safety and effectiveness; and ensure proposed labeling contains truthful claims for safety and effectiveness, and adequate directions for use and warnings against misuse.

Reviews supplements and amendments to previously approved NDAs, which must be thoroughly reviewed for efficacy and safety in acting on a supplement; reviews periodic reports submitted by sponsors on drugs approved for marketing; reviews adverse reaction and other safety reports. Makes medical decision in each case as to whether the indicated population of a previously approved NDA should be expanded, ensures changes in the labeling are required, and whether the information available supports approval of the supplement.

Reviews the summaries of pharmacologists and chemists as part of the decision-making process and determines whether to approve an application. Makes science-based recommendations that an NDA or a supplement submission be approved, is incomplete on specific points, or be disapproved that an IND be continued, modified, or placed on clinical hold.

Assigned work is in medical specialty, as much as this is practicable, based on the types of applications received. Drug submissions assigned for review will include drugs whose evaluation will be difficult and require mature professional judgment. Physicians within the Division are considered the Agency's foremost specialists in pain medicine, and in appropriate clinical trial design for evaluation of drugs intended to treat such conditions.

Contributes on a multidisciplinary scientific team to arrive at a conclusive medical opinion; considers a variety of types of information, such as research findings and clinical studies on pain medicine related drugs. Provides authoritative comments on research set-ups and new techniques within the team and, in the context of industry meetings, with drug company representatives. Prepares correspondence requesting information on facts of the case inadequately presented.

Consults with other medical specialists and scientists within FDA, and other government agencies, universities, hospitals, and clinics. May recommend that additional studies be made under an FDA contract or that consideration of a drug be given by a specially constituted committee of physicians and scientists.

Keeps abreast of the progress in medical and related sciences by reviewing the scientific literature, attending conferences, and participating in staff seminars, at which, cases and special topics are discussed.

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 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.

Specialized Experience/Desirable Qualifications:

The applicant should have:

- Broad experience in clinical pain management. Experience with clinical trials and technical writing are desirable.
- Knowledge of clinical, medical, and scientific literature and current clinical activities relating to new drugs and biologics in the assigned therapeutic area.
- Professional knowledge of, and skill in applying theories, concepts, principles, and practices of medicine sufficient to serve as a recognized technical authority and consultant in a broad operating program that affects national and international interests, including the well-being of the American public.
- Demonstrated ability to advise senior colleagues and agency officials on a broad operating program and to manage significant projects that represent an important segment of the agency's operating programs.
- Knowledge and understanding of current FDA, Center, and OND regulations, policies, and procedures pertaining to safe and effective drugs and biologics.
- Expert written and verbal communications skills to provide advice and guidance to senior management and employees and prepare a variety of written reports and documents.
- Expert analytical, fact-finding, and investigative techniques and skills to carry out the Division's mission.

Basic Requirements:

Applicants must have a Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent, from a school in the United States or Canada, or from a foreign medical school. Degrees for graduates from a school in the United States or Canada 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.

Degrees for graduates of foreign medical schools 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.

Applicants also must possess a current, active, full, and unrestricted license as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

In addition to the degree and licensure requirements, applicants also must have had at least four years of graduate training in the specialty of the position to be filled or equivalent experience and training in regulatory science and/or medical research.

Desirable Education:

Certification by or eligibility for the American Board of Pain Medicine (ABPM) and/or American Board of Internal Medicine (ABIM) in Hospice & Palliative Medicine is required.

Conditions of Employment:

Security Clearance:

This position requires a Public Trust background investigation; the incumbent has access to sensitive, proprietary, or financial information.

Ethics Requirements:

This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of

Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

How to Apply: Please submit resume to: ond-employment@fda.hhs.gov. For questions please contact OND External Recruitment Team at ond-employment@fda.hhs.gov or 301-796-0800. Please reference **source code: 20-048EG** in the subject line.

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