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 Executive Programs (OEP)
Advisory Committee Management Branch (ACMB)
Division of Advisory Committee and Consultant Management (DACCM)

Position: Pharmacist

Series: AD-0660

Location(s): Silver Spring, MD (White Oak Campus)

Travel Requirements: 25% travel or less

Application Period: October 20, 2020 through October 26, 2020

Salary: Starting salary at $86,335 and is commensurate with qualifications (CURES Bands B and C)

Conditions of Employment: United States Citizenship

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) 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 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. CDER is looking for leaders with a commitment to scientific excellence and innovative thinking to lead a dynamic and diverse organization.

The Office of Executive Programs (OEP) oversees a variety of Center-wide programs, including executive project management, the Center's executive secretariat function, scientific advisory committees, training and development, CDER's ombudsman, and program and administrative management.

The Advisory Committee Management Branch (ACMB) in the Division of Advisory Committee and Consultant Management (DACCM), Office of Executive Programs (OEP), Center for Drug Evaluation and Research (CDER) supports DACCM's role by ensuring the work and information surrounding advisory committees is complete and accurate, and the utilization of external experts is well planned and executed in a timely manner.

Position Summary:

The **Pharmacist** serves as a Designated Federal Officer (DFO) for the advisory committees responsible for implementing the administrative aspects of hosting Advisory Committee Meetings under the Federal Advisory Committee Act requirements.

Supervisory responsibilities:
N/A

Duties/Responsibilities (Band B):

Assists the Designated Federal Officer (DFO) in preparing and gathering information pertaining to the Advisory Committee Meetings under the Federal Advisory Committee Act requirements. In this capacity, the incumbents develop, coordinates, and ensures the initiation of new documents, correspondence, and policies.

Applies professional knowledge of therapeutic product use of regulated products (including drugs, biologics and devices) and analytical expertise to identify solutions to data interpretation between industry applicants and the review divisions within CDER. these problems are sensitive in nature and have high public interest pertaining to the public health's impact.

Gathers information, identifies problems, and develops a scientific, risk-based approach to assignments that are appropriate and consistent with Agency/Office policy. Reviews and evaluates existing regulations and guidance. Works with the assigned DFO and other key personnel inside and outside the Office, Center, (FDA), and other governmental agencies (e.g.,

NIH, CDC, CMS, VA) to interpret and implement Federal advisory committee laws, that assists in making recommendations for appropriate and individual meetings.

Performs in-depth research using a variety of sources such as U.S. treatment guidelines, PubMed, Up-to Date, ClinicalTrials.gov on current clinical practice guidelines and product use related to specific advisory committee meeting topics.

Participates in discussions with other Agency professionals, to share and collaborate on best practices concerning the approach to future advisory meetings surrounding sensitive and complex public health topics.

Assists with research activities to understand the scientific basis for the advice and recommendation that the Agency seeks for a specific application(s) or therapeutic topic. Uses research findings to recommend the appropriate use of external expertise and specific experts for advisory committee meeting, agency directed assignment, and committee membership.

Facilitates premeeting discussions between the Chair and Review Division to establish the scope of discussion for a specific meeting and may serve as meeting facilitator to assure advisory meeting ground rules and other protocols are maintained and followed.

Works with CDER staff members in the collection and organization of information for considering a wide range of issues presented to the advisory committee meetings (errors in prescribing, dispensing, accidental exposures, drug abuse, etc.) associated with FDA-regulated prescription and non-prescription medications. Identifies pharmaceutical issues associated with preventable harm that also have a large impact on the public health.

Reviews pharmacy practice, clinical application and therapeutic use of drugs, statutory and regulatory issues that have a major impact on the Division and numerous offices across the Center in order to develop the competing and affected products list for the advisory committee meetings, the incumbent assesses the list for potential impacts by Advisory Committee (AC) meeting outcomes Analyzes issues and recommends varied and multiple statutes, regulations and policies in determining effective resolution of issues related to advisory committee meetings. These reviews and analyses are used when soliciting and vetting candidates for advisory committee meetings to determine if a candidate has an interest in a product or entity related to the specific meeting being held; this minimizes any potential for financial or intellectual conflicts of interest.

Attends assigned Advisory Committee meetings; adjourns the meetings when he/she determines, in consultation with senior branch and division staff, that adjournment is in the public interest; approves or calls meetings of the advisory committees; develops or approves meeting agendas; determines when meetings should be closed in conformity with legal requirements; assumes responsibility for maintaining all committee records.

Follows established principles to arrange meetings that are reasonably accessible and at convenient locations and times; publishes adequate advance notice of meetings in the Federal Register; opens advisory committee meetings to the public (with some exceptions); makes available for public inspection, subject to the Freedom of Information Act, papers and records, including detailed minutes of each meeting; and maintains records of expenditures.

Duties/Responsibilities (Band C):

Serve as a Designated Federal Officer (DFO). Oversees all administration pertaining to Advisory Committee Meetings under the Federal Advisory Committee Act requirements. In this capacity, the incumbents develop, coordinates, and ensures documents, correspondence, and policies are sufficiently finalized for supervisory review and approval.

Applies expert knowledge of therapeutic products use of regulated products (including drugs, biologics and devices) and analytical expertise to identify solutions and makes recommendations to controversial data interpretation between industry applicants and the review divisions within FDA, these problems are most complex and sensitive and have high public interest pertaining to the public health's impact.

Works closely with key personnel inside and outside the Office, Center, (FDA), and other governmental agencies (e.g., NIH, CDC, CMS, VA) to interpret and implement Federal advisory committee laws, that will determine recommendations for appropriate and individual meetings.

Leads in-depth research activities using a variety of sources such as U.S. treatment guidelines, PubMed, Up-to Date, ClinicalTrials.gov on current clinical practice guidelines and product use related to specific advisory committee meeting topics.

Represents CDER externally with others HHS advisory committees. Provides information on FDA practices surrounding advisory meeting and committee management. The DFO is considered a subject matter expert and shares their technical expertise among scientists, physicians and other professionals to facilitate their participation in the committee meetings as well as create knowledge sharing practices with future special government employees (SGE's).

Serves as a liaison to other Agency committees, organizations, and as a participant in national conferences and other discussions regarding committee meeting logistics responsibilities and public health topics. In this capacity, the incumbent works to develop close working relationships among professional organizations with interest in the therapeutic and public health areas, watchdog groups and academia.

Prepares annual committee management and advisory committee topical reports for OMB, Congress, and similar hearings. The incumbent provides substantial input in the develop of

other special reports, justifications of needs and participates in relevant discussions with other Agency professionals.

Applies technical knowledge to interpret the scientific basis for the advice and recommendation that the Agency seeks for the drug application or therapeutic topic under review. Identifies and recommends the appropriate use of external expertise and specific medical specialty and expert required for the advisory committee meeting, agency directed assignment, or committee membership.

Facilitates premeeting with Committee Chair and Review Division to establish the scope of discussion for a specific meeting. Serves as advisory committee meeting facilitator to ensure the meeting is ran appropriately. Maintains the boundaries of the discussion in-meeting using CDER's committee management principles and practices.

Applies scientific knowledge in the areas of pharmacy practice, clinical application and therapeutic use of drugs in combination with FDA's statutory and regulatory laws, regulation and polices to frame advisory committee meetings issues.

Reviews, evaluates and interprets pharmacy practice, clinical application and therapeutic use of drugs, statutory and regulatory issues that have a major impact on the Division and numerous offices across the Center in order to develop the competing and affected products list for the advisory committee meetings, the incumbent reviews and edits the list for potential impacts by Advisory Committee (AC) meeting outcomes. Analyzes issues and applies varied and multiple statutes, regulations and policies in determining effective resolution of issues related to advisory committee meetings.

Manages very strict timelines surrounding committee meeting logistics, public notice requirements, and meeting material, ensuring a multitude of dependent activities are complete. The environment is enormously high pressure and requires responsibilities be performed accurately and completely.

Approves or calls meetings of the advisory committees; Serves as an active participates in Advisory Committee meetings to discuss committee actions; evaluates and makes decisions; develops or approves meeting agendas; may serve as chairs in the absence of the appointed chairperson; determines when
meetings should be closed in conformity with legal requirements; maintains all committee records.

Provides committee recommendations from committee reports or summary statements. Engages the appropriate agency official to assist the committee members reach consensus or resolve split decisions; communicates the reasons for differences of opinion among committee members.

Follows established principles to arrange meetings that are reasonably accessible and at convenient locations and times; publish adequate advance notice of meetings in the Federal Register; opens advisory committee meetings to the public (with some exceptions); make available for public inspection, subject to the Freedom of Information Act, papers and records, including detailed minutes of each meeting; and maintain records of expenditures.

Education Requirement:
A doctoral degree in Pharmacy that is recognized by the Accreditation Council for Pharmacy Education (ACPE) or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Licensure:
Applicants must be licensed to practice pharmacy in a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

Medical: Applicants must be able to distinguish basic colors.

Basic Required Experience:
In addition to the licensure, educational, and medical requirements described above, applicants must possess three years of progressively higher-level graduate education leading to a Ph.D. degree, PharmD. or equivalent doctoral degree and a minimum of one year of professional Pharmacy experience that is equivalent to at least the next lower band level.

Position's Desired Skills and Experience: AD-660 (Band B)

- Ability to solve a variety of moderately challenging problems to develop and apply new strategies to problems not resolvable by standard methods.
- Ability to communicate orally and in writing.
- Ability to interact with various organizations, academia and the regulated industry.
- Knowledge of the Federal Food, Drug, and Cosmetic Act.
- Knowledge of the FDA advisory committee process.
- Knowledge of the FDA drug review process.
- Knowledge of and demonstrated experience in pharmacy practice to understand the processes by which drug products are selected, prescribed, and dispensed.
- Knowledge of measures used to monitor patients for therapeutic response and toxicity of a wide range of drug products.
- Professional knowledge of, and skill in applying theories, principles, concepts, standards, and methods in the field of pharmacy to consult, advise and provide guidance on complex scientific, regulatory and compliance issues.
- Knowledge of project management principles related to the administrative logistics surrounding meeting management.

Position's Desired Skills and Experience: AD-660 (Band C)

In addition to the Band B position desired skills and experience, Band C applicants should have the:

- Ability to solve a variety of highly complex problems and to develop and apply new strategies to problems not resolvable by standard methods.
- Mastery and skill in applying expertise in advanced professional theories, principles, concepts, standards, and methods to conceive and apply experimental theories and new development applications to extend and modify theories, concepts, and assumptions; resolve unique or novel problems, conditions, and issues; and significantly alter standard practices, equipment, devices, processes, and known techniques.
- Expert knowledge of broad operating programs to advise senior colleagues and agency officials and manages significant projects that represent an important segment of the agency's operating programs.

EEO Responsibility:

The incumbent is responsible for furthering the goals of equal employment opportunity (EEO) by taking positive steps to assure the accomplishment of affirmative action objectives and by adhering to non-discriminatory employee practices regarding race, color, religion, sex, national origin, age, or handicap. Specifically, as a manager, incumbent initiates non- discriminatory practices and affirmative action for the area under his/her supervision in the following: 1) merit promotion of employees and recruitment and hiring of applications; 2) fair treatment of all employees; 3) encouragement and recognition of employee achievements; 4) career development of employees; and 5) full utilization of their skills.

Equal Employment Opportunity Policy

The United States Government does not discriminate in employment based on 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. Click here to find out additional information about the 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; and 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.

Conditions of Employment:

Security Clearance: 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.

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: Submit resume or curriculum vitae with cover letter by **October 26, 2020** 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 Code: **T-20-130-B/C**

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