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: Health Science Administrator

Series: AD-0601

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

Travel Requirements: Up to 25% travel

Application Period: October 13, 2020 through October 19, 2020

Salary: AD-601 Starting salary at $86,335 and is commensurate with qualifications (CURES Bands and C)

Conditions of Employment: United States Citizenship is required.

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 **Health Science Administrator** 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):

As a Designated Federal Officer (DFO) for the advisory committee, is responsible for implementing the administrative aspects of hosting Advisory Committee Meetings under the Federal Advisory Committee Act requirements. Responsibilities include the identification, appointment and onboarding of Experts and Consultants, Advisory meeting logistics and public participation. The incumbent also runs and reports on the committee management activities to include financial operations, charter renewals and annual review requirements for assigned meetings.

Performs the preliminary administrative and scientific review of Investigational New Drugs (IND), New Drug Applications (NDA) licensing or other health science issues to be presented to fully understand the scientific basis for the advice and recommendation that the Agency seeks for a specific application(s). Uses results to recommend the appropriate use of external expertise and specific experts for assigned advisory committee meeting, agency directed assignment, or committee membership.

Performs 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. Collaborates and fully participates in discussions with other Agency professionals regarding products and entities that could potentially be impacted by the outcome of an assignment Advisory Committee (AC) meeting.

Responsible for the completion of committee member nomination documents, charter renewal documents, quarterly and end of year Federal Advisory Committee Act (FACA) reports, and annual reports to Congress across multiple committees.

Administers the on-going review of scientific issues assigned to the various advisory committees. Provides a wide variety of information to the consultants (committee members) as a background for

reviewing and evaluating issues. Collects and provides information considered to be essential for members to have in order to adequately evaluate the assignment. Assists in producing summary statements of committee findings and recommendations for use by the senior officials of the agency based on committee evaluation.

Participates in developing and implementing programs, plans, and communications to identify and review and resolve issues that have a major impact on the Division and numerous offices across the Center. 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.

Participates in the handling of the administrative logistics and support for consultants throughout the duration of their special advisory subcommittee assignments. Such assignments may involve special meetings with principal investigators of studies submitted to the committee for review and with Agency scientists also involved with these issues.

Develops communication plans to select the best-qualified committee members for subcommittees and other special assignments. Uses the CDER Advisory Committee Members and Consultants database to identify and maintain knowledge of the comparative competencies of practitioners and scientists working in the field of interest in order to recommend outstanding candidates from the diverse scientific disciplines needed to maintain a balance of skills and the highest level of competence in the committee membership.

Approves or calls meetings of the advisory committees; serves as an active participant in the Advisory Committee meetings to discuss committee actions; evaluates and makes decisions to adjourns the meetings when it is in the public interest; 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.

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):

Serves as a Designated Federal Officer (DFO) for the advisory committees responsible for overseeing the administrative aspects of hosting, commencing and closing Advisory Committee Meetings under the Federal Advisory Committee Act requirements. Responsibilities include the identification, appointment and onboarding of Experts and Consultants, Advisory meeting logistics and public participation. The incumbent also runs and oversees reporting on the committee management activities to include financial operations, charter renewals and annual review requirements for assigned meeting.

Performs the preliminary administrative and scientific review of Investigational New Drugs (IND), New Drug Applications (NDA) licensing, or other health science issues to be presented to fully understand the scientific basis for the advice and recommendation that the Agency seeks for a specific application(s). Uses results to recommend the appropriate use of external expertise and specific experts for assigned advisory committee meeting, agency directed assignment, or committee membership.

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. Collaborates and leads discussions with other Agency professionals regarding products and entities that could potentially be impacted by the outcome of an assignment or Advisory Committee (AC) meeting.

Develops and implements programs, plans, and communications to complete committee member nomination documents, charter renewal documents, quarterly and end of year Federal Advisory Committee Act (FACA) reports, and annual reports to Congress across multiple committees.

Oversees and manages the ongoing review of scientific issues assigned to the various advisory committees. Provides a wide variety of information to the consultants (committee members) as a background for reviewing and evaluating issues. Collects and provides information considered to be essential for members to have in order to adequately evaluate the assignment. Produces a summary statement of committee findings and recommendations for use by the senior officials of the agency based on committee evaluation.

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.

Serves as a liaison to other Agency committees, organizations, and as a participant in national conferences and other discussions of problems related to the committees' responsibilities. The incumbent develops close working relationships among scientists, physicians and other professionals concerned with similar problems. Responsibilities may include preparing special reports for OMB, Congress, and similar hearings, the incumbent aids in developing special reports, justifications of needs, etc.

Analyzes issues and applies Federal statutes, regulations, and policies to recommend effective solution of issues related to advisory committee meetings. Implements suggested solutions to resolve issues that have a major impact on the public health and programs administered by DACCM and other Center program offices associated with the planning and implementation of advisory committee meetings. The incumbent may be required to address program time and resource constraints, processing delays and issues relating to meeting logistics.

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. The incumbent also discusses committee actions with leaders of regulated industry, health and professional organizations and other governmental Agencies.

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.

Manages the administrative logistics and support for consultants throughout the duration of their special advisory subcommittee assignments. Such assignments may involve special meetings with principal investigators of studies submitted to the committee for review and with Agency scientists also involved with these issues.

Develops and implements programs, plans, and communications to select the best-qualified committee members for subcommittees and other special assignments. Uses the CDER Advisory Committee Members and Consultants database to identify and maintain knowledge of the comparative competencies of practitioners and scientists working in the field of interest in order to recommend outstanding candidates from the diverse scientific disciplines needed to maintain a balance of skills and the highest level of competence in the committee membership.

Approves or calls meetings of the advisory committees; Serves as an active participant in the Advisory Committee meetings to discuss committee actions; evaluates and makes decisions to adjourns the meetings when it is in the public interest; 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.

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 maintain records of expenditures

Education Requirement: AD-601

Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Position's Desired Skills and Experience: AD-601 (Band B)

- Knowledge of the FDA advisory committee process.
- Possession of interpersonal skills and proven communication ability to develop strategic contacts and outreach to external members of the healthcare community, including other federal agencies, members of professional organizations, and patient safety groups.

- Ability to identify problems, gather information, draw conclusions, recommend solutions, prepare papers and reports for publication, provide advice to other regulatory scientists, and negotiate acceptance and implementation of recommendations.
- Knowledge of the Federal Food, Drug, and Cosmetic Act.
- Knowledge of the FDA drug review and regulatory process

Position's Desired Skills and Experience: AD-601 (Band C)

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

- Ability to recognize the need for and then develop new procedures to solve critical or novel problems and/or to perform more refined analyses.
- Mastery of the theories, principles and methods in regulatory science and possibly any associated scientific disciplines sufficient to allow the employee to review a variety of complex industry applications, to apply new scientific and technological developments to novel and critical problems which cannot be solved by the use of conventional methods; and to extend and modify approaches, precedents and methods in order to resolve and prevent obscure and unprecedented problems.

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 19, 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-20-129-B/C

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

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