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: Regulatory Counsel

Series: AD-0301

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

Travel Requirements: Up to 25% travel

Application Period: September 10-September 16, 2020

Salary: Salary starts at $102,663 and is set commensurate with qualifications. (CURES Band 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 **Regulatory Counsel**, for the Advisory Committee Management Branch (ACMB) is in the Division of Advisory Committee and Consultant Management (DACCM), Office of Executive Programs (OEP), Center for Drug Evaluation and Research (CDER).

Supervisory responsibilities:
N/A

Duties/Responsibilities:

Clarifies and provides comments on the statutes, regulations, policies, procedures, and implications relevant to advisory committees for a variety of audiences (e.g. sponsor, external experts, CDER review teams, CDER regulatory specialist, and other Center's within the Agency). Gathers and organizes information on the Division's past and current practices and engages in sophisticated analyses of complex regulatory and policy issues in collaboration with CDER staff and Office of the Commissioner staff in carrying out its regulatory mission.

Works in conjunction with the Office of Regulatory Policy (ORP) and Office of Chief Counsel (OCC) to resolve a broad range of issues concerning the application of FDA's enabling statutes, pertinent regulations, and/or general laws affecting the operation of the Federal Government. Assists in aligning the division's practices with the outcomes of these resolutions. Assignments are often complex and require extensive research.

Assumes responsibility for ensuring that the Division's practices and policies regarding the appointment of Special Government Employees (SGE), chartering and renewing technical advisory committees, screening external participants for participation in advisory committee meetings and assignments, and the conduct of meetings and assignments, are consistent with Conflict of Interests law, the Federal Advisory Committee Act, Food and Drug Administration Amendments Act, Government in the Sunshine Act, among other statutory requirements and policies.

Works on assignments affecting the regulation of drug products in conjunction with the CDER Office of New Drugs (OND), related to conflict of interest screening, public transparency, intellectual bias, and products affected by the outcome of the advice received by external experts. Drafts or critically reviews documents embodying policy and program proposals and decisions on matters affecting the regulation of these products, including decisions on the policy interests.

Prepares draft responses to correspondence received directly from regulated industry, the press, advocacy groups, or other offices within the Executive Branch related to advisory committee matters including disclosure of scientific data, regulatory history, financial disclosures, and other matters. Adheres to internal protocol and clearance procedures to ensure all stakeholder perspectives and interests are considered. Inquiries may be industry-wide in scope or have broad health implications and result changes in practices, or interpretations of laws governing FDA and FDA's policy.

Advises CDER program offices on procedures and methods for implementing current, new, and revised regulations regarding to 21 CFR Part 14 regulations and 5 CFR Part 2635 and on the sufficiency and procedural adequacy of proposed policy statements and policy initiatives pertaining to the same.

Uses resources such as Westlaw, LexisNexis, MediRegs, the US Code, the Code of Federal Regulations, the Federal Register, and others, to conduct research regarding established precedents in order to develop and support legally sufficient policies.

Education Requirement: AD-301

A juris doctorate degree from an accredited institution of higher learning.

Position's Desired Skills and Experience: AD-301

A juris doctorate degree from an accredited institution of higher learning. Knowledge of federal regulatory programs is highly desired. Demonstrated analytical ability, judgement, discretion in executing Food & Drug Law activities.

Demonstrated ability to identify and analyze problems; weigh the relevance and accuracy of information; generate and evaluate alternative solutions; and make recommendations.

- Demonstrated skill in the analysis, evaluation, and interpretation of complex Federal statutes and regulations

- Demonstrated ability to work independently and collaboratively across organizational boundaries
- Knowledge of the Federal Advisory Committee Act
- Knowledge of the Federal Food, Drug, and Cosmetic Act
- Knowledge of FDA regulatory practice, policies, and procedures
- Ability to communicate orally and in writing and work with staff at all levels of the organization and varying levels of domain expertise; demonstrated ability to collaborate across boundaries to build strategic relationships and achieve common goals
- Ability to organize time effectively, determine priorities, and move work forward

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 **September 11th, 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-20-148-C

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

FDA is an equal opportunity employer.