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)

Position: Associate Director for Therapeutic Review

Pay Plan-Series: AD-0602/E

Location(s): Silver Spring, MD

Travel Requirements: 25%

Application Period: 9/7/2020 – 11/6/2020

Salary: Starting at $195,000 (Cures Band E)

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) 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. The Office of New Drugs's (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:

The Associate Director for Therapeutic Review (ADTR) position within the review divisions provides direction and leadership to scientific and clinical review staff involved in the complex task of regulating and evaluating new drugs and biological products. The staff are engaged in the review of human drug trials in the United States, in review of NDAs and biologics license applications (BLAs) for marketing drugs and therapeutic biologics in this country, and in regulating OTC drug products. On behalf of the Division Director, the ADTR provides leadership in the management of scientific and clinical review staff performing human drug trials in the US via INDs, reviewing NDAs and BLAs, and regulating OTC drug products for a multidisciplinary staff that regulate and evaluate new drugs and biological products for a designated therapeutic class of drugs.

The position executes delegated authority for approval or non-approval of NDAs, BLAs, supplemental applications, IND requests, OTC drug, and monograph products other than those delegated to the subordinate offices. Such decisions can be of the most controversial, complex, or critical nature. The position also provides consultation and expert advice on the evaluation of drugs to the Division and Office Director. The incumbent serves as a scientific advisor and consultant on the functions and programs that are the responsibility of the Division. The incumbent will frequently be expected to represent FDA at professional meetings, committees, and working groups, as well as prepare and present testimony to Congress.

Supervisory responsibilities: Supervise and evaluate staff who serve as experts in their field. Provides occupational-specific technical and administrative direction and supervision 25 percent or more of the time to subordinate supervisors and staff performing the work and functions of the organizational unit. Obtains resources and identifies strategic objectives for the organization.

Professional Experience/Desirable Qualifications:

- Knowledge of NDAs, BLAs, supplemental applications for investigational new drug (INDs) requests, OTC drug, and monograph products. Ability to drive collaboration, empower staff, provide expert advice and consultation, coordinate program activities, and spearhead important program initiatives. Knowledge of leadership principles and concepts regulating and evaluating new drugs and biological products. Ability to manage and lead a diverse interdisciplinary staff.

Minimum Educational requirements include:

0602 series: Applicants must have a Doctor of Medicine or Doctor of Osteopathy degree from an accredited medical school. Graduates of foreign medical schools must be certified by the

Education Commission for Foreign Medical Graduates (ECFMG). After obtaining a Doctor of Medicine or Doctor of Osteopathic Medicine degree, a candidate must have had at least 4 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. Applicants 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.

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 in regard to race, color, religion, sex, national origin, age, disability, sexual orientation, affiliation or non-affiliation with a labor organization, political affiliation, and status as a parent or gender identity. Specifically, as a manager, the incumbent initiates nondiscriminatory practices and affirmative action for the Center in the following: (1) merit promotion of employees and recruitment and hiring; (2) fair treatment of all employees; (3) encouragement and recognition of employees' achievements; (4) career development of employees; and (5) full utilization of their skills. Click here to find out additional information about the Equal Employment Opportunity (EEO) for federal employees & job applicants.

Conditions of Employment:

Security Clearance:

This position requires a Public Trust security clearance and 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 or curriculum vitae with cover letter 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: 20-093EG** in the subject line.

The Department of Health and Human Services is an equal opportunity employer with a

smoke free environment.

FDA is an equal opportunity employer.