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 Generic Drugs, Office of Bioequivalence

Position: Director, Office of Bioequivalence

Pay Plan-Series: AD-0601

Location(s): Silver Spring, Maryland

Travel Requirements: Up to 10%

Application Period: 2/19/2020-3/19/2020

Salary: Starting at $197,241

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 Office of Bioequivalence (OB) oversees the thorough evaluation of any clinical data required to support Abbreviated New Drug Application (ANDAs) and develops medical judgment. OB establishes bioequivalence specifications for drug products and develops guidelines for bioequivalence reviews, industry protocols, and studies. OB supports the development and implementation of standards for the safety and effectiveness of generic drugs.

Position Summary:

The Director Plans, manages, organizes, and directs all the regulatory review operations, program segment(s), functions, and activities of OB as carried out by Division Directors, Deputy Directors, subordinate supervisors and/or team leaders and a highly trained and skilled staff of professionals responsible for the regulatory review mission of the Office.

Supervisory responsibilities:

Manages a multi-disciplinary program, providing leadership and management oversight to 200+ subordinate support staff and division directors.

Duties/Responsibilities:

- Applies knowledge of administrative and program management principles and skills to carrying out the mission of the Office as well as to address and solve unusual and often precedent setting problems associated with the regulatory review program segment(s). Seeks and develops the most cost effective and fiscally responsible methods to conduct these program segment(s) and to solve these problems.

- Initiates decision-making processes and documents and participates fully in discussions and decisions concerning Office and OGD plans, programs, and activities, both in strategic planning and in the actual determination, allocation, and administration of Office programs, functions, and activities. Provides authoritative advice and assessments of the impact of actual and proposed Administration or Congressional actions on the programs, functions, and activities of the Office and how they interrelate to CDER activities and priorities.

- Develops and implements OB and its Division policies and plans and makes critical decisions and provides expert advice and counsel concerning approaches and options that are sound and feasible in relation to Office and OGD goals and objectives and Federal budgetary and economic realities. Continually evaluates budget, fiscal, and administrative controls to manage Division program segment(s) and services. Develops and makes recommendations for the enhancement and improvement of the mission and functions of the Office.

- Represents the Office and OGD in dealing and negotiating within CDER and with individuals representing organizations such as the Congress; other Federal agencies; State, local, and foreign governments; the regulated industry; professional and industry organizations; and public interest groups. Directs the preparation, clearance, and finalization of Office responses to inquiries covering all aspects of the programs, functions, and activities of the Office.

- Directs the preparation of analyses of the impact of proposed changes to Agency laws and regulations which affect the functions, program segment(s), and activities of the Office. Decides on changes and additions to the functions, program segment(s), and activities of the Office

necessary to implement new legislation or regulations and develops various scenarios for dealing with expansion or contraction of Office functions, program segment(s), and activities.

- Directs the implementation of new laws and regulations which impact on the mission of the Office. This includes responsibility for the initiation and implementation of new policies, systems, procedures, and organizational structures.

- Provides occupational specific technical and administrative direction 25 percent or more of the time to three or more subordinate employees performing the work and functions of the organization.

EEO Responsibility:

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.

The incumbent, in conjunction with his/her supervisor, develops an affirmative employment plan for the area supervised including appropriate objectives and goals; and monitors and periodically assesses progress. Keeps informed of, supports, and communicates to employees EEO policies, plans and programs. Seeks out and utilizes available resources, including appropriate personnel generalists/specialists, EEO specialists, and training resources in conducting these responsibilities. Incumbent will be appraised on the effectiveness of his/her performance.

Professional Experience/Desirable Qualifications:

- Executive leadership experience with an established track record in leading drug development and knowledge of regulatory standards for safety and effectiveness of human drugs.
- Demonstrated management of organizations of significant size and complexity.
- Effective communicator who can drive collaboration, empower staff, and is committed to the Public Health mission.

Desirable Education:

Minimum Education Requirement: Meets the Office of Personnel Management (OPM) Individual Occupational Requirements (IOR) for General Medical and Health Series, 0601. Please review the entire IOR to confirm the minimum education requirements at the following link: General Medical and Healthcare Series, 0601

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 Financial Disclosure Report (OGE 450) 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: http://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/default.htm.

How to Apply: All qualified candidates can submit curriculum vitae and cover letter in which you describe why you feel you are uniquely qualified for this position electronically to Whitney Flickinger, Whitney.Flickinger@fda.hhs.gov.

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