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)
Office of Drug Evaluation Sciences (ODES)

Position: Office Director, Office of Drug Evaluation Sciences

Pay Plan-Series: AD-0601/G

Location(s): Silver Spring, MD

Travel Requirements: 25%

Application Period: 6/8/2020 – 8/7/2020

Salary: Starting at $197,241 (Cures Band G)

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 compensated 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 Center for Drug Evaluation and Research (CDER) is responsible for regulating prescription drugs, including new drugs, generic drugs, biological products and biosimilars as well as over-the-counter drugs. CDER's drug regulatory responsibilities include premarket review of new drugs and generic drugs; maintenance of the OTC drug monograph system; monitoring of all marketed drug safety and promotion activities; review, monitoring, and enforcement of drug quality during the entire drug life cycle; and ensuring drug products in the market comply with the law.

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 manufacturers in support of New Drug and Investigational New Drug applications (NDA/IND), and to determine if candidate drugs are safe and effective.

Position Summary:

Within OND, the (sub) Office of Drug Evaluation Sciences (ODES) provides direction and guidance on the design and application of endpoints and instruments (e.g., biomarkers/surrogate endpoints, clinical outcome assessments (COA), bioinformatics) that support drug development, provides direction and guidance on safety analytic tools and approaches, and supports research in OND relevant to drug development and regulation. ODES provides support across OND therapeutic divisions, in collaboration with other offices in the CDER and other FDA centers, and works closely with external stakeholders including patient, academic, and industry organizations to advance methods and tools supporting drug development and review.

As the Office Director, the incumbent provides direction and leadership to multiple divisions involved in the complex task of regulating and evaluating new drugs and biological products. These divisions are engaged in the oversight of human drug trials in the United States, in review of new drug applications (NDAs) and biologics license applications (BLAs) for marketing drugs and therapeutic biologics in this country, and in regulating over-the-counter (OTC) drug products. The ODES Directorship represents an extraordinary opportunity for an exceptional leader to meet the challenges of emerging science at the crossroads of drug development.

Supervisory responsibilities: Manages a multi-disciplinary program, providing leadership and management oversight to subordinate support staff and division directors. 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.

Duties/Responsibilities:

The incumbent serves as the Director for the ODES. On behalf of the Super Office Director, OND, the incumbent is responsible for supervising a staff at varying grade levels performing scientific work that has a direct impact on public health. The incumbent supervises and coordinates several cross-cutting regulatory and scientific groups or programs such as the OND research program, the biomarker qualification program, the biomedical informatics and safety analytics group, and the clinical outcomes assessment (COA) group. The incumbent also assures that the input from groups and programs within ODES provided to regulated industry and to OND divisions on IND drug development issues is appropriate, thoughtful, thorough, and timely. The incumbent also addresses a broad range of issues concerning the application of FDA's relevant statutes, regulations, guidance documents, standard operating procedures, and other policy documents related to the regulation of new drug products about the application of biomarkers, surrogate endpoints, COAs, and other novel approaches. The incumbent is responsible for leading efforts related to adoption and implementation of drug development tools, technologies, and analytic approaches across review divisions.

Provides leadership, guidance and/or regulatory expertise to address and solve complex regulatory issues consistent with technological developments or new scientific evidence and provides innovative solutions to complex problems. Makes decision or provides concurrence on issues of this nature presented by ODES division leadership. Maintains an expert knowledge and keeps abreast of new findings by reading scientific literature as it relates to study endpoints and labeling development and the drug review process. Serves as a CDER/Agency resource for information on current and state of the art concepts e regulatory health management involving study endpoints and labeling development.

EEO Responsibility: 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:

- The selected candidate will possess a demonstrated track record of experience and thought leadership in a field relevant to the broad range of ODES responsibility, including translational medicine, biomarker or COA development; drug development experience in academia, government, or industry; experience building multidisciplinary teams to collaborate across a heavily matrixed environment and achieve strategic objectives.

Minimum Education Requirements:

This is an interdisciplinary position that may be filled in the following series: General Health Scientist (0601). Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/0600/general-health-science-series-0601/.

Desirable Education:

M.D. degree, or advanced healthcare-related professional degree (Ph.D. in relevant disciplines, PharmD) with extensive experience.

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.

Equal Employment Policy: 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. Click here for additional information on Equal Employment Opportunity (EEO) for federal employees & job applicants

How to Apply: Please submit resume or curriculum vitae with cover letter to Ond-employment@fda.hhs.gov by August 7, 2020. For questions please contact OND External Recruitment Team at Ond-employment@fda.hhs.gov or 301-796-0800. Please reference **source code: 20-049EG** in the subject line.

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