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)
Immediate Office (IO)

Position: Deputy Super Office Director for Drug Safety

Pay Plan-Series: AD-0602/F

Location(s): Silver Spring, MD

Travel Requirements: 25%

Application Period: 6/1/2020 – 7/1/2020

Salary: Starting at $210,000 (Physician Pay Table – Band F)

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 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 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 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:

This position is in the Immediate Office of OND and has primary responsibility for the implementation and management of all post-market (PM) drug safety programs and activities within OND, and the following:

Provides technical and administrative direction and leadership to subordinate employees within the organization involved in the complex task of regulating and evaluating new drugs and biological products. Act with full authority in carrying out the variety of day-to-day operations of the PM drug safety program including understanding all projects underway and an intimate understanding of major policy issues. Serves as the Supervisor for the Safety Policy and Research Team (SPRT) that is currently in the OND IO and provides direction and oversight for implementation of the post-market safety processes and procedures within OND, including drug safety research. The SPRT has responsibility for assuring consistent implementation of post-market safety statutory and regulatory requirements, and standard practices per the Manual of Policies and Procedures (MaPP) across OND (e.g., for risk evaluation and mitigation strategy (REMS), post-market requirements (PMRs), post-market commitments (PMCs), safety labeling changes (SLCs), and drug safety communications (DSCs)). The position provides direction and supervision to SPRT in their role in assuring consistent post-market safety management across OND. In addition, the SPRT is involved in research related to post-market safety that informs policy and procedure development.

Supervisory responsibilities:

Assists in managing 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.

Recruits, retains, and develops the talent needed to achieve a high-quality diverse workforce that reflects the nation, with the skills needed to accomplish organizational performance objectives while supporting workforce diversity, workplace inclusion and equal employment policies and procedures. Recommends employee promotions and recognitions; approves leave; within-grade increases; extensive overtime; employee travel; implements performance modifications and takes corrective actions as appropriate.

Reviews succession plans and responsible for mentoring and developing the growth of Division Directors for Safety. Interviews candidates and recommend the appointment, promotion, or reassignment of employees to such post market safety related positions. Mentor staff members to include contract personnel to ensure that all new personnel receive appropriate training and that experienced regulatory personnel stay abreast in advances in scientific practices and methodologies.

Duties/Responsibilities:

The Deputy Super Office Director for Drug Safety will provide direction and supervision to:

- Implements and manages the new Drug Safety Teams (DSTs), assuring that these are properly functioning consistent with the DST charter. Select the DST OND Co-chair for each DST. The Drug Safety Teams serve as the fundamental unit of post-market drug safety surveillance and management. Coordinates with the divisions through close interactions with the PM safety staff in OND, including the Deputy Directors for Safety (DDS) and the Safety RPMs. Chair regular meetings of the DDS group to assure consistency of application of policy and procedures, to discuss and review challenging post-marketing issues, and to discuss potential changes/updates to policies and procedures.

- Integrates OND PM safety management efforts with those of other CDER offices involved in PM safety (including with Office of Surveillance and Epidemiology [OSE], Office of Pharmaceutical Quality [OPQ], and the Office of Generic Drugs [OGD], Office of Compliance [OC]), and with PM drug safety project management and the Drug Risk Management Board (DRMB) in the Center Director's (CD) office serving in a liaison function. Develops PM safety policies, procedures, and structures (e.g., Drug Safety Teams [DSTs]) according to evolving knowledge, principles, and capabilities for PM drug safety (i.e. work closely with the OND Policy Office and other policy offices in CDER (and

FDA), with the SPRT, and with the OND research program in the Office of Drug Evaluation Sciences).

- Runs the post-market safety drug program for the OND organization. Identifies specific activities needed to achieve desired outcomes. Serves as the principal advisor to the Office Director and provides leadership and technical direction to scientific and regulatory review staff engaged in PM drug safety review and evaluation; provides scientific, clinical, regulatory and technical authority on all medical and scientific decisions and judgment in connection with the review and evaluation of the post-market drug safety, including on post-market requirements, post-market commitments, post-market pharmacovigilance planning, and post-market safety findings.

- Provides PM safety-related clinical expertise to OND's clinical offices and divisions as well as interdisciplinary scientific staff and other staff members in coordinating activities related to PM safety including pharmacovigilance planning, implementation, and PM drug safety management. Reviews and provides input, as appropriate, to relevant OND staff on all planned major post-marketing determinations (e.g., DSCs, new post-approval safety labeling changes and boxed warnings, drug withdrawals for safety, requirement for new safety-related PMRs post-approval, requirement for new REMS post-approval, or release of REMS other than when consistent with the original REMS proposal).

- Provides oversight and technical clinical expertise on critical aspects of post-marketing safety, particularly those that involve the broadest and most controversial, sensitive, and complex subjects (i.e. issues often require technical expertise, integrated evaluation throughout Center components (including with OSE, with the CD office and with the DRMB), and sensitive coordination with other Agency components because of their potential impact on FDA programs and public health. The Deputy Super Office Director for Drug Safety is an authoritative expert not only on the PM safety processes and procedures but also on all areas of drug regulation.

- Provide consultation and expert advice on the evaluation of PM drug safety to Office Senior Leadership, to other FDA Centers, other government agencies, foreign governments, and international organizations. Serve as scientific advisor and consultant to the Office Director and higher-level Agency officials on the functions and programs that are the responsibility of the office. The incumbent will frequently be expected to represent FDA at professional meetings, committees, and working groups.

- The Deputy Super Office Director for Drug Safety is expected to have expertise on new approaches to PM safety management, and if and how such new approaches should be incorporated into OND practices and procedures. The incumbent will be involved in evaluating, and as appropriate, implementing new approaches that can enhance OND

and CDER's PM drug safety management such as broader application of Real-World Data (working collaboratively with OSE and the Office of Medical Policy), harvesting of social media information, or linkages of large safety-related databases, among others.

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 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, or 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 of applicants; (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.

Professional Experience/Desirable Qualifications:

- The Deputy Super Office Director for Drug Safety for OND will be an innovator who seeks to improve PM drug safety and will have the ability to greatly impact within the broader CDER organization. The selected candidate will possess extensive pharmaceutical industry experience and has a proven record of leading an organization.

Key requirements will include:

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.

Desirable Education:

N/A

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: 20-052EG** in the subject line.

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