TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Clinical Policy and Programs (OCPP)
Office of Orphan Product Development (OOPD)

Position: Office Director, Office of Orphan Product Development (OOPD)

Series: 602-Physician; 601-Health Science Administrator; 301-Regulatory Counsel

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

Travel Requirements: 5%

Application Period: February 18, 2021-March 15, 2021

Salary: $163,962-$310,000

Conditions of Employment:

- Citizenship Requirement: You must be a U.S. Citizen to be considered for this advertisement unless explicitly stated otherwise.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Selective Service Registration: All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- Background Investigation Requirement: All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- Time-in-Grade Requirement: If you are applying as a current Federal employee, you must meet the time-in-grade requirements described in the Qualifications section, generally, 52-weeks of comparable experience at the next lowest grade.

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 Office of Clinical Policy and Programs (OCPP) is to advance the public health by developing, leading, and executing programs and cross-cutting initiatives that support FDA's centers in making effective, safe, and innovative medical products available to the American people. OCPP also coordinates and supports patient engagement activities across the medical product centers to foster awareness and collaboration with patients, their advocates and the FDA, with the goal to strengthen and modernize key functions to enhance communication to our stakeholders and further elevate the role of patients in our work in medical product development.

The Office of Orphan Products Development (OOPD) was established to implement designation and grants programs described by the Orphan Drug Act (ODA) to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. In fulfilling that task, OOPD evaluates scientific and clinical data submissions from sponsors to identify and designate products as promising for rare diseases and OOPD also furthers advancement of scientific development of such promising medical products through the OOPD grant programs. Also, the office works on rare disease issues with the medical and research communities, professional organizations, academia, governmental agencies, industry, and rare disease patient groups. OOPD implements various provisions of the Orphan Drug Act and other statutory provisions, by which sponsors qualify for orphan product development incentives such as clinical research tax credits and marketing exclusivity. The incumbent serves as the Director OOPD and Supervisory Physician. The incumbent carries out the professional functions of identification, research evaluation, development and promotion of availability of FDA regulated orphan products that may be useful for rare diseases or conditions.

Position Summary:

Serves as the Director, OOPD providing technical, clinical and administrative oversight for OOPD. Provides senior expertise in advancing potential therapies in populations without effective remedies by evaluating preclinical, historical, and clinical data relating to the safety and effectiveness of the products for the prevention, diagnosis, or treatment of rare diseases or conditions. Serves as the leading agency authority and expert in rare disease regulation, integrates knowledge and experience to resolve problems, modify procedures, and develop and interpret complex policies to meet novel challenges and conditions, where actions taken and solutions devised cut across other functional areas within the agency. Directs the implements new laws, regulations, and guidances that influence the mission of the organization. Initiates and implements new policies, systems, procedures, and organizational structures.

Serves as the leading agency authority and expert occupying a key position in the FDA effort to promote the development of orphan products that are needed by specific patient populations, but are unavailable due to inadequate research and lack of committed commercial sponsorship. Administers the Orphan Drug Designation program, the Rare Pediatric Disease Designation program, the Humanitarian Use Device Designation program, and Grant programs for Orphan Product Clinical Trials, Natural History, and the Pediatric Device Consortia. Oversees the Orphan Drug Designation program that provides orphan status to drugs and biologics, which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S, or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Oversees the success of the Orphan Drug Designation program and leads the office to evaluate scientific and clinical data submissions from sponsors to identify and designate products as promising for rare diseases and to further advance scientific development of such promising medical products. Establishes the priorities for all orphan programs and professional staff within the OOPD based on workload, patient needs, regulatory and policy needs, and available data. Provides scientific and technical guidance on programs and processes, and responds to concerns of stakeholders.

Supervisory responsibilities:

Manages a multi-disciplinary program, providing leadership and management oversight to subordinate support staff (41+). Provides guidance, direction, resolves disputes and strives to ensure that members of each team have what is necessary to perform their jobs to the best of their abilities. Sets the quality standards for written orphan products reviews that determine if the applications have satisfied the requirements of the relevant orphan product regulations. Provides oversight to ensure orphan product review summarizes all relevant pre-clinical and clinical data related to the product's orphan product potential for development. Provides oversight to the Orphan Grant Programs to uphold the standards for the conduct of the project officer staff, the review of the grant applications, grant funding, monitoring grant progress and

determines the appropriateness of continued funding. Maintains contacts with appropriate individuals and organizations.

Duties/Responsibilities:

Organizational Management: Manages an Office.
Program Management: Runs a multi-disciplinary program. Identifies specific activities needed to achieve desired outcomes. Organizational staffing patterns are primarily homogeneous, but may also have staff in various scientific, professional, technical, or administrative occupational series.
Resource Management: Monitors and reports on resources needed to run an Office or a multi-disciplinary program
Personnel Performance Management: Counsels and rates immediate subordinates.
Human Capital Management: Identifies employee competencies necessary to meet organizational capabilities goals.

Equal Employment Opportunity 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.

- 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.
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.

Professional Experience/Desirable Qualifications:

Strong leadership and skill in leading/directing large organizations, including strategic planning and problem solving, making policy and programmatic decisions and overseeing office management, i.e., hiring, professional development, IT development, etc.
In-depth knowledge of the Agency's policies, and scientific and regulatory requirements and review programs as they relate to medical products.

Specialized experience to include: Ph.D or equivalent degree or equivalent years of experience in regulatory policy and/or health science

Key requirements will include:
Your resume must demonstrate that you have experience in **carrying out the professional functions of identification, research evaluation, development and promotion of availability of FDA regulated orphan products that may be useful for rare diseases or conditions.** Strong background in policy and regulatory guidance documents. Talent for building partnerships and collaborations with stakeholders in public and private arenas.

Desirable Education:

Physician, 0602 Requirements: One-year probationary period may be required; Official transcripts required; Must possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States. Degree must have been accredited by the Council on Medical Education of the American Medical Association (external link); Association of American Medical Colleges (external link); Liaison Committee on Medical Education (external link); Commission on Osteopathic College Accreditation of the American Osteopathic Association (external link), or an accrediting body recognized by the U.S. Department of Education (external link) at the time the degree was obtained.

Healthcare Series, 0601 Requirements: Bachelor's or graduate/higher level degree: major study

in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education (external link) at the time the degree was obtained.

Conditions of Employment:

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) 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 and unofficial school transcript/s by March 15, 2021 to: Tammy.Russell@fda.hhs.gov. For questions please contact Tammy Russell at email address or 301-796-1045.

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

FDA is an equal opportunity employer.