TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Commissioner (OC)
Office of Clinical Policy and Programs (OCPP)

Position: Director, Office of Clinical Policy and Programs

Series: 0601

Location(s): Silver Spring, MD

Travel Requirements: 5%, Occasional travel may be expected

Application Period: May 11, 2020 – May 26, 2020

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

Conditions of Employment: United States Citizenship is required.

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 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 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.

Residing in the Office of the Commissioner, the Director of OCPP has authority over the Office of Pediatric Therapeutics, the Office of Orphan Products Development, the Office of Combination Products, the Office of Clinical Policy, including the Office of Good Clinical Practice, and the Patient Affairs Staff.

Position Summary:

The Director serves as the Vice-Chair for the cross-Agency Combination Products Policy Council and the Orphan Drug Products Policy Council. The incumbent provides support to Center Directors and other executives in the FDA medical product centers as needed and advises on all programs related to the functional areas under his/her purview as they relate to the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. Incumbent provides leadership and direction to subordinates and oversite of operational activities and develops short/long term goals for OCPP program areas. Incumbent may serve as a representative of FDA on areas under purview. Some other critical, high-level functions will reside in OCPP.

Supervisory responsibilities:

Manages a multi-disciplinary program, providing leadership and management oversight to Office Directors and subordinate support staff (120+).

Duties/Responsibilities:

- Manages the Office – maintaining and establishing decision making framework across the organization. Runs a multi-disciplinary program.
- Identifies specific high-priority, high-impact 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.
- Monitors and reports on resources needed to run the Office or a multi-disciplinary program in the Agency.
- Counsels and rates immediate subordinates and identify 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
- In-depth knowledge of the Agency's policies, and scientific and regulatory programs as they relate to medical products
- Strong background in science

- Talent for building partnerships and coalitions with stakeholders in public and private arenas

Basic Requirements:

A 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 (https://ope.ed.gov/accreditation/) at the time the degree was obtained.

In addition to the educational requirement, application must show experience in providing scientific leadership in formulating, developing, implementing and evaluating public health programs and scientific studies/surveys designed to improve public health programs.

Desirable Education:

This position has an education requirement. You are strongly encouraged to submit a copy of your transcripts (or a list of your courses including titles, credit hours completed and grades). Unofficial transcripts will be accepted in the application package. Official transcripts will be required from all selectees prior to receiving an official offer. Foreign Education: Education completed in colleges or universities outside the United States may be used to meet the education requirements. You must provide acceptable documentation that the foreign education is comparable to that received in an accredited educational institution in the United States.

Conditions of Employment:

Security clearance and background checks:

The position requires a Public Trust background investigation; the incumbent has access to sensitive, proprietary, or financial information. 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 reinvestigation or supplemental investigation may be required at a later time. Applicants are also advised that all information concerning qualifications is subject to investigation. False representation may be grounds for non-consideration, non-selection and/or appropriate disciplinary action.

Ethics Requirements: Ethics pre-clearance is required.

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 vita, cover letter and transcript to: **Jobs@FDA.HHS.GOV.** A complete application package must be received by 11:59 PM (EST) on the closing date of May 26, 2020 to receive consideration. **All applicants are required to reference source code: 20-001T21OC in the subject line and submit the following supporting document types (s):**

- Resume or curriculum vitae
- Cover Letter
- College Transcripts (Unofficial)

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