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 the Center Director (OCD)
Controlled Substance Program (CSP)

Position: Science Policy Advisor

Series: AD-0601

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

Travel Requirements: 25% or less

Application Period: November 19, 2020 through November 23, 2020

Salary: Starting salary of $121,316 (CURES Band D)

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 (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 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 (OTC) and prescription drugs, including biological therapeutics and generic drugs. CDER is looking for leaders with a commitment to scientific excellence

and innovative thinking to lead a dynamic and diverse organization.

This position is in the Office of the Center Director, Immediate Office. The position is part of a new strategic group in the IO, led by the Associate Director for Controlled Substances, that is focused on proactively identifying emerging issues with controlled substances and pursing strategic programs, initiatives, and policies that promote public health by enabling appropriate access to controlled substances. Issues handled at this level typically involve complex, often controversial, and sensitive public health topics.

Position Summary:

The **Science Policy Advisor** identifies emerging issues and has extensive knowledge of related statutes, regulations, policies, and procedures to identify potential FDA actions and initiatives to target these emerging issues. The incumbent advises on activities and complex issues involving controlled substances and cultivates relationships with top level Center, Agency, or Departmental officials to push initiatives forward. Potential projects include initiatives, task forces, and program responses to address emerging issues involving problematic use of controlled substances or substances with potential for abuse, including opioids, stimulants, benzodiazepines, and cannabis and cannabis-derived products.

Supervisory responsibilities:
N/A

Duties/Responsibilities:

Acts as a public-health focused subject matter expert supporting the Associate Director for Controlled Substances on strategic controlled substances programs and policies, serves as a key liaison to Agency-level staff, other Federal agencies, industry and academia on controlled substances issues, represents the Center on internal and external committees, task forces and working groups, and presents Center policies and procedures in public forums. Facilitates intra- and inter-agency interactions to develop and implement strategy and policies that require coordination and negotiations among stakeholders.

Provides analysis and advice to the Associate Director for Controlled Substances, and other senior management in the Center, including the Center Director, on agency-wide programs or issues involving controlled substances and public health. Formulate appropriate program responses to minimize risks associated with problematic use of controlled substances. These issues and potential responses may be identified through broad professional knowledge, technical expertise, monitoring of academic publications, proactive attendance and outreach at conferences, comprehensive understanding of the full range of Center regulatory policies, programs and procedures, knowledge of the statutes and regulations enforced by the Agency, and personal observation and experience with many divergent sources, both within and outside the Agency.

Pursues proactive stakeholder engagement to increase awareness among internal and external stakeholders of emerging issues with controlled substances and ongoing FDA initiatives and proactive policies, in coordination with strategic partners CDER Office of Communications (OCOMM), Professional

Affairs and Stakeholder Engagement (PASE), and with FDA professional staff from other Centers or Offices as needed.

Supports public scientific workshops focused on topics like emerging trends in illicit and prescription abuse of controlled substances, prescribing guidelines, and drug development paradigms for novel treatments and treatment approaches.

Serves as a project manager responsible for independently overseeing and influencing a high-level portfolio of initiatives, task forces, and program responses to address emerging issues involving problematic use of controlled substances or substances with potential for abuse. Responsibilities include:

- Leading the development, monitoring, coordination, and implementation of complex, high-level initiatives and activities
- Preparing and maintaining a project plan for activities and task forces as necessary/appropriate.
- Attending and/or leading other Center, Agency, and Interagency committees, task forces, or working groups related to controlled substances
- Planning and coordinating projects and meetings across a varied and diverse team/working group of FDA stakeholders
- Serving as the primary point of contact for the up-to-date monitoring of the status of project activities and progress and reporting the status to the Associate Director for Controlled Substances
- Identifying risks that may adversely impact the pursuit of strategic activities and policies around controlled substances or that impact ongoing activities. Advising team members and senior Center management, including the Associate Director for Controlled Substances, of the potential impact and recommending solutions

Develops, recommends, coordinates, and implements program improvements and new procedures designed to enhance program performance on controlled substance activities broadly throughout CDER

Education Requirement: AD-601:

Candidates must meet education requirements of 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 at the time the degree was obtained.

Position's Desired Skills and Experience: AD-601 (Band D):

- Extensive experience in a professional or administrative field to make decisions or recommendations significantly changing, interpreting, or developing important public policies or programs.
- Experience and knowledge with FDA regulations and laws, historical and legal precedents, regulations, guidelines, policies and procedures that may be relevant for controlled substances.

- Experience and knowledge with data gathering methods and analytical/evaluative techniques to conduct assessments of health communication strategies and to draw valid conclusions.
- Ability to collaborate with stakeholders to formulate communication and marketing strategies that affect local, national, and international policies and trends.
- Extensive experience with applying project management techniques and concepts to manage large, complex projects with diverse stakeholders.
- Ability to work independently, proactively identify priorities and push work forward with activities and tasks with minimal oversight.
- Ability to identify and analyze problems; weighs relevance and accuracy of information; generates and evaluates alternative solutions; makes recommendations.
- Ability to lead people towards meeting the organization's vision, mission, and goals.

EEO Responsibility:

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 regarding race, color, religion, sex, national origin, age, or handicap. Specifically, as a manager, incumbent initiates non- discriminatory practices and affirmative action for the area under his/her supervision in the following: 1) merit promotion of employees and recruitment and hiring of applications; 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.

Equal Employment Opportunity Policy:

The United States Government does not discriminate in employment based on 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 to find out additional information about the 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; and 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.

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 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:

Submit resume or curriculum vitae with cover letter by **November 23, 2020** to: CDER-OCD-OEP-Hires@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research (CDER) with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions please contact Ashley Corum-Lawson, Supervisory Administrative Officer, Ashley.Corumlawson@fda.hhs.gov. Please reference Job Code: T-20-198-D

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