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)

Application Period: November 22, 2021- December 22, 2021

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Senior Science Policy Advisor

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $144,128
*Starting salary is minimum of band and may be set higher, commensurate with experience.

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

This position is being filled under a stream-lined 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 this authority.
Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

Introduction

The Food and Drug Administration (FDA or the Agency) is the regulatory, scientic, 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.

The Office of the Center Director (OCD) plans, administers, coordinates, and evaluates overall Center scientific, management, and regulatory programs, plans and policies, as well as provides leadership and direction for all Center activities.

The Controlled Substance Program (CSP) is focused on proactively pursuing activities and policies to identify, mitigate, and manage emerging issues with controlled substances. Through these efforts, the CSP will continue the mission of promoting public health by enabling appropriate access to controlled substances.

Duties/Responsibilities

The Senior Science Policy Advisor will serve as the Center lead on policy efforts surrounding the research and regulation of cannabis in addition to working on issues related to other controlled substances with potential for abuse.

Conducts research involving cannabis and cannabis-derived compounds for potential medical uses in the Unites States, as part of FDA's mission to protect and promote the public health by ensuring the safety, efficacy, and quality of medical products, including drugs. Supports scientific research in the medical uses of cannabis, will consider potential and emerging safety implications and thereby be involved and lead efforts that are complex, unprecedented, legislative and policy focused. Program segments, functions, and activities of the Center related to cannabis and other controlled substances, includes the incumbent having knowledge of related statutes, regulations, policies, and procedures to identify potential FDA actions and initiatives to target these emerging issues surrounding cannabis use and its safety.

Coordinates and manages special projects including initiatives, task forces, and program responses to address emerging issues involving the problematic use of controlled substances or substances with potential for abuse with a particular focus on cannabis and cannabis-derived products in addition to opioids and other controlled substances.

Serves as a key public health subject matter expert supporting the Associate Director for Controlled Substances on strategic controlled substances programs and policies especially those surrounding cannabis and cannabis derived products by exploring and considering CDER activities that will support the development of new drugs from cannabis. Serves on internal and external committees, task forces, and working groups requiring coordination, leadership, or representation by the Associate Director for Controlled Substances (CSP).

Establishes and maintains collaborative intra/inter Agency relationships to develop and implement strategies and policies requiring negotiation among stakeholders. Serves as a key liaison to Agency-level staff (including staff at the level of the Center Director and

Office of the Commissioner), other agencies or units within the Department of Health and Human Services (HHS) (including the Assistant Secretary for Health, Office of the Secretary, National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMSHA), and Centers for Disease Control and Prevention (CDC), other Federal agencies (including the Drug Enforcement Administration (DEA), the Office of National Drug Control Policy (ONDCP), Congress, as well as high -ranking industry and academia officials in the area of controlled substances. Presents Center policies and procedures as an authoritative expert. Leads the development of regulations, petition responses, and other written statements of Agency policy.

Consults with staff at all levels of the Agency and identifies areas of disagreement. Resolves disagreements through meetings or the use of decision memoranda and articulates any policy consensus reached through this process.

Develops and implements Center policies, plans, and programs, drafts and reviews proposals grounded in scientific research for new regulations and policy statements, and makes expert recommendations on high priority matters affecting CDER/CSP to the Associate Director for CSP, and other senior management in the Center, including the Center Director. Assignments involve the organization's regulatory programs, strategies, and activities with a particular focus on cannabis and cannabis derived products, in addition to work on other controlled substances. Interprets, applies, or revises complex legislation, regulations, concepts, and principles to intervene and or facilitate Agency support in public health crisis related to the abuse of controlled substances. Responsibilities provide the basis for current and long-range Agency policies and programs of nationwide public concern that address the public health emergency regarding cannabis, cannabis derived products and other controlled substances abuse.

Serves as a senior 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:

- Leads the development, monitoring, coordination, and implementation of complex, high-level initiatives and activities; prepares and maintains a project plan for activities and task forces as necessary and appropriate.
- Identifies risks that may adversely impact the pursuit of strategic activities and policies related to cannabis and cannabis derived product as well as controlled substances; and recommend solutions to address risks and potential impacts.
- Assists with resource management activities in collaboration with the Associate Director for CSP.

Supervisory Responsibilities: N/A

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- 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.
- 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.
- Males born after December 31, 1959 must be registered with the Selective Service.
- One-year supervisory probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. 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 later.

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
    a. ***Qualified*** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
    b. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position*.

Minimum Qualification Requirements: AD-0601

Degree: 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.

Professional Experience:

- Demonstrated knowledge of FDA regulations and laws, historical and legal precedents, regulations, guidelines, policies, and procedures that may be relevant to controlled substances (including cannabis and opioids).
- Expert knowledge of data gathering methods and analytical/evaluative techniques to conduct assessments of health communication strategies and to draw valid conclusions.
- Understands and keeps up-to-date on local, national, and international policies and trends as well as academic publications that affect the organization and shape stakeholders' views; is aware of the organization's impact on the external environment.
- Extensive experience with applying project management techniques and concepts to manage large, complex projects with diverse stakeholders.
- Master ability to identify and analyze emerging problems that are highly complex, sensitive, technical, or controversial in nature; weigh relevance and accuracy of information; generate and evaluate alternative solutions; and make expert recommendations that are both scientifically sound and politically feasible.
- Master ability to provide authoritative recommendations and guidance on policies that have broad health implications, concern precedent-setting interpretations, and are industry-wide in effect.

Desired Experience:

- Mastery and thorough understanding of a professional or administrative field to make authoritative decisions or recommendations significantly changing, interpreting, or developing important public policies or programs.
- Ability to lead people toward meeting the organization's vision, mission, and goals; demonstrate expert skill in working effectively with high-ranking decision-makers.
- Ability to serve as a widely recognized advisor on major policy issues.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. For more information about this requirement, please visit the U.S. Department of Education website for Foreign Education Evaluation.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/High Risk
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 Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information please visit the FDA Ethics web page: https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity

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

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.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

How to Apply

Submit resume with cover letter by **December 22, 2021** to: CDER-OCD-OEP-Hires@fda.hhs.gov. Candidate resumes may be shared with hiring official within 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 Reference ID: T-21-701-E.

Announcement Contact

For questions regarding this Cures position, please contact Ashley Corum-Lawson, Supervisory Administrative Officer, Ashley.Corumlawson@fda.hhs.gov.

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

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