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 Medical Policy (OMP)
Office of Medical Policy Initiatives (OMPI)
Division of Medical Policy Programs (DMPP)

Application Period: July 11, 2022 – July 24, 2022

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: Deputy Division Director  
Series: AD-0601

Location(s): Silver Spring, Maryland  
Salary: Starting at $148,484

Work Schedule: Full Time  
Cures Band(s): Band E  
Full Performance Band Level: Band E

Travel Requirements: 25% or less

Bargaining Unit: Non-Bargaining 8888

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) 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 and prescription drugs,
including biological therapeutics and generic drugs.

The mission of the Office of Medical Policy Initiatives includes providing oversight and direction for the development of medical policies and procedures pertaining to the drug development and drug approval process and to collaboratively enhance professional and patient labeling. The mission of the Division of Medical Policy Programs includes coordinating and collaborating with relevant program areas to ensure optimal FDA scientific and technical input for ongoing policy initiatives, developing and managing new sciences and technology policy initiatives pertaining to the drug development, drug approval, and post market surveillance process, and representing the Office on center and agency working groups with activities relevant to OMP programs and initiatives.

Duties/Responsibilities

As the Deputy Division Director, the incumbent is directly responsible for the implementation of complex and precedent setting medical policy programs and initiatives across a broad range of medical/clinical and technological subject matter, including drug development and drug approval processes, consumer-directed medical information, professional labeling, and other subject matter areas as assigned by the Division Director. The incumbent develops concept and/or issue papers, guidance, regulations, and operating procedures and identifies program areas, coordinating committees, and other FDA constituencies affected by planned program initiatives, and ensures appropriate collaboration with affected parties. The Deputy Division Director is independently responsible and has final authority over several policy projects that focus on professional and patient labeling, drug approval and drug development processes, as assigned, and oversees all aspects of the project deliverables. This includes the quality and timeliness of the deliverables, ensuring optimal FDA scientific and technical input are provided on the projects, and identifying risk mitigation steps and procedures are in place to ensure the goals of the projects are met.

Supervisory Responsibilities: Supervises and evaluates a staff of professionals who serve as experts in their fields. 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 of the organization. Hears and resolves complaints from subordinate staff, referring group grievances and more serious unresolved complaints to a higher-level supervisory authority. Provides employees with resources and information that ensure a safe and healthy work environment. Recommends employee promotions and recognition. Approves leave, within-grade increases, extensive overtime, and/or employee travel. Implements performance modifications and takes corrective actions as appropriate.

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 at a later time.

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.

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.

**Education Requirement:** General Medical and Healthcare Series, AD-0601. 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 US Department of
Education at the time the degree was obtained. For more information please see: OPM
Occupational Series Qualification Requirements

**Desired Education:** Our ideal candidate will possess a Juris Doctor degree or a masters or
doctoral degree in the physical sciences.
Professional Experience:

**Desired Professional Experience:** Our ideal candidate will possess experience with drug policy development, applying knowledge of regulatory practice, policies, and procedures. Experience in leading an organization.

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](https://www.ed.gov/).  

Security Clearance Requirements:

Background Investigation/Security Clearance is required: 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.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request
information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

**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](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](https://www.fda.gov/about-fda/jobs-and-training-fda/eeo)

**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](https://www.fda.gov/about-fda/jobs-and-training-fda/eeo) or [how to contact an agency](https://www.fda.gov/about-fda/jobs-and-training-fda/eeo).

**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 or curriculum vitae with cover letter by **July 24, 2022**, to: Tammy.Sauter@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. Please reference Job Reference ID: **T-49-15-2022**

Announcement Contact
For questions regarding this Cures position, please contact Tammy Sauter, Lead Management and Program Analyst Tammy.Sauter@fda.hhs.gov.

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