Title 21 Cures Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Vaccines Research and Review (OVRR)
Immediate Office of the Director (IOD)

Application Period: September 26, 2023 – November 22, 2023

Area of Consideration: The Public
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 Office Director
Series: 0401 (Biologist), 0403 (Microbiologist), 0601 (General Health Scientist), 0602 (Physician)

Location: White Oak Campus, Silver Spring, MD
Salary: Series 0401, 0403, 0601 = Table 1 – Starting at $177,123 and is set commensurate with education and experience.
Series 0602 = Table 3 – Starting at $210,000 and is set commensurate with education and experience.

Work Schedule: Full Time
Cures Band: Band F
Telework Eligible: Yes – as determined by the agency policy.

Full Performance Band Level: Band F
Travel Requirements: 25% or less

Bargaining Unit: 8888

Note: Incentives may be authorized; however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment, or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

This position is being filled under a streamlined 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 is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe, and that all such products marketed in the United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated. FDA’s programs are national in scope and effect, and the agency’s activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

The Center for Biologics Evaluation and Research (CBER) is a Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. CBER’s mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergens, tissues, and cellular and gene therapies. CBER protects and advances the public health by ensuring that biological products are safe, effective, and available to those who need them. CBER also provides the public with information to promote the
safe and appropriate use of biological products.

The Office of Vaccines Research and Review (OVRR) protects and enhances public health by assuring those available vaccines, allergenic extracts, and related product are safe and effective.

Duties/Responsibilities
The incumbent serves as the Deputy Office Director for the Office of Vaccines Research and Review (OVRR) under the Center for Biologics Evaluation and Research (CBER) and fully participates with managing the Office. The Deputy Office Director, in conjunction with the Office Director, oversees the planning, development, and direction of strategies and risk- and issued-based actions related to the safety, efficacy, and quality of the nation’s infectious diseases vaccines and related biologics, as well as allergenics, live biotherapeutic products, and bacteriophage. The Deputy Office Director, in conjunction with the Immediate Office of the Director staff and the Office Director, supports the Office's review of investigational new drug (IND), emergency use authorization, and original and supplemental biologics license applications. The Deputy Director serves as a principal advisor to and spokesperson for the Office Director on Office-wide and Office-level strategies and actions. This position reports to the OVRR Office Director.

Specifically, the Deputy Office Director will:
- Advise the Office Director and senior Center officials in formulating and developing Office-level strategic and tactical plans, programs, initiatives, objectives, goals, priorities, and legislative initiative recommendations.
- Provide Office-level oversight and support of regulatory reviews and actions on vaccines and related biologics, including allergenics, live biotherapeutic products, and bacteriophage.
- Act for the Director in monitoring activities throughout the Office, including reviewing priority risks and issues for consistency of approach and providing coordinative leadership to Office staff in resolving research and regulatory risks and issues.
- Participate in and contribute to meetings and conferences with top-level agency/departmental officials, industry representatives, senior program managers and subject matter specialists, counterparts from other Federal, State, and local governmental agencies, foreign government representatives and others to discuss and explain policies, plans and programs as they relate to Office activities.
- Serve as the Office Director designee, as assigned, on agency committees, councils, and work groups and on external advisory committees.
- Participate as an Office representative in meetings with various organizations, institutions, and agencies, including the World Health Organization (WHO), the Pan American Health Organization, National Regulatory Authorities, non-governmental organizations, industry, and academia.

Supervisory responsibilities:
Organizational Management: Assists in managing an Office.
Program Management: Runs a program of singular discipline focus in the Center. Oversees or coordinates multiple functional activities.
Resource Management: Monitors and reports on resources needed to run an Office in the Center.
Personnel Performance Management: Counsels and rates immediate subordinates.
Human Capital Management: Identifies employee competency gaps.

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 respective OPM Qualification Standards or below Education/Graduate Training Requirements 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.

**Education/Graduate Training Requirements:**

**0401 Series (Biologist)**

Candidates must possess the required OPM individual occupational requirements to qualify for the appropriate series applicable to the position.

Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.

**0403 Series (Microbiologist)**

Education: A bachelor’s degree or higher in biology, microbiology, or virology. The degree must be from an accredited program or institution.

**0601 Series (General Health Scientist)**

Candidates must possess the required OPM individual occupational requirements to qualify for the appropriate series applicable to the position.

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.

**0602 Series (Physician)**

Education: A degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent.

AND

Graduate Training: In addition to a degree, a candidate must have had at least one year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the United States or Canada.

**Desired Education:** For 0401, 0403, and 0601 series, candidates would ideally have a master’s degree, doctoral degree, or both in Biology or Microbiology.

**Desired Professional Experience:**

- For 0602 series, an ideal (Physician) candidate would possess an active medical license in at least one state or U.S. federal jurisdiction.
- Experience managing or assisting in managing a scientific research office.
- Experience developing short- and long-term programmatic goals.
- Experience communicating scientific concepts to a lay audience.
- Supervisory experience is highly desirable.

**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: 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.

**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**
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**
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 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**
Please submit electronic resume or curriculum vitae (please be sure to clearly define the number of years using month and year training completed, in addition to describing duties performed during that time period), copy of your unofficial transcripts, copy of your active medical license(s) (if applicable), copy of your board certification(s) (if applicable), SF-50 (if applicable), and letter of interest with "CBER/OVRR Deputy Office Director" in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through November 22, 2023.

**Announcement Contact**
For questions regarding this Cures position, please contact CBERHumanCapital@fda.hhs.gov.

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

*FDA is an equal opportunity employer.*