Associate Director for Rare Diseases and Special Populations
Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of the Center Director (OCD)

Summary:

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 U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Center for Biologics Evaluation and Research (CBER) is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

Overview

Area of Consideration: Public
Open & Closing Date: August 30 – September 20, 2024
Salary Range: $235,000 - $340,795
Band: G
Occupational Series: 0602
Duty Location: Silver Spring, MD
Remote Job: No
Telework Eligible: Yes
Travel Required: 25% or less
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band G
Supervisory Status: Yes
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 8888

You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

Duties:

Serves as the Associate Director for Rare Diseases and Special Populations and participates with the Director and Deputy Directors in providing leadership in the development, implementation, execution, management and direction of the Center's Rare Disease Program and other initiatives related to advancing the development of CBER-regulated products for diseases and conditions that are rare and/ affect other special populations such as pediatric populations.

From an overall perspective, advises the Director, Deputy Directors, senior FDA officials and others on activities related to diseases and conditions that are rare and/or affect pediatric populations that affect Center wide programs, projects, and initiatives, or have an impact on policy development and execution of long-range program goals.

Specifically, the Associate Director will:

- Provide executive advice and assistance and medical direction to a multi-disciplinary workforce engaged in the execution of nationwide programs and the daily management of the Center's activities related to diseases and conditions that are rare and/or affect special populations such as pediatric populations, and as necessary assists in developing, establishing, or recommending policy to the Deputy Directors and Center Director.
- Advise and assist the Director and Deputy Directors in formulating, developing, and shaping CBER's short- and long-range goals related to diseases and conditions that are rare and/or affect special populations such as pediatric populations.
- Coordinate rare disease activities with internal partners within CBER, such as staff and leadership in the Immediate Office of the Director, Office of Therapeutic Products, Office of Vaccines Research and Review, Office of Blood Research and Review, and Office of Regulatory Operations, as well as across the agency, including the Office of Orphan Products, Development, Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health.
- Evaluate the Center's overall activities related to CBER-regulated products for rare diseases and other special populations such as pediatric populations and, as necessary, develops, establishes, or recommends initiatives or priorities to the Director and Deputy Directors.
- Collaborate with the Associate Director for Policy and Director of the Office of Regulatory Operations to coordinate activities related to the regulation, development, and review of products for pediatric populations with internal partners within CBER as well as across the agency, including the Pediatric Review Committee (PeRC), and offices overseen by the FDA Chief Medical Officer, such as the Office of Pediatric Therapeutics and the Office of Clinical Policy.
- Provide leadership from a clinical perspective on issues related to good clinical practice and human subject protection policies, in coordination with internal partners within CBER as well as across the agency, such as the Office of Clinical Policy. Represents the Center on the FDA IRB and serves as CBER's Human Subject Protection Liaison.
- Participate in identifying Center/ Agency needs in terms of national goals and in developing the direction of medical programs and policies related to biological products for diseases and conditions that are rare and/or affect special populations such as pediatric populations to ensure that Agency objectives are accomplished and that interagency and multi-agency obligations and commitments are met; analyzing and providing authoritative evaluations and recommendations concerning the initiation, curtailment, consolidation of major drug programs and medical activities and in the economical deployment of Center resources to efficiently accomplish the Agency's legislated responsibilities in matters related to biological products.
- Participate with the Director, Deputy Directors, senior officials, and others in testifying before Congress on Agency programs and medical activities. As an expert on medical activities related to biological products, provides authoritative advice, guidance, assistance, interpretations and recommendations to key agency officials, program directors, scientific and professional personnel, departmental representatives, intra/inter-governmental counterparts, and others on issues related biological products for diseases and conditions that are rare and/or affect special populations such as pediatric populations.

Requirements

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- 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. Please go to http://www.sss.gov for more information.
- One-year probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation Requirement: 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.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.
- **If you are serving or have served in the last 5 years as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment.** You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. *See Political Appointee FAQ - OPM for more.*

Desired Skills/Experience:

- An ideal candidate would possess an active medical license in at least one state or U.S. federal jurisdiction.
- Mastery of advanced medical theories, practices, and techniques as applied to drug evaluation typified by the completion of an approved medical residency program supplemented by clinical or research experience.
- Mastery knowledge of the Federal Food, Drug, and Cosmetic Act; experimental design; theories and practices to use in new drug evaluation; and current clinical and research data and activities related to biological product development especially for diseases and conditions that are rare and/or affect special populations such as pediatric populations.
- Mastery expert knowledge of the FDA regulatory science and associated disciplines to allow consideration of issues from a variety of complex INDs, IDEs, BLAs, PMAs, 510(k)s, master files, supplements, and amendments from manufacturers of products intended for use diseases and conditions that are rare and/or affect special populations such as pediatric populations.
- Effective written communication skills to develop policy, guidance(s) to industry, internal procedures, and responses to Congressional inquiries, and to provide advice to CBER senior officials.
- Effective oral communication skills to exercise tact, diplomacy, and technical expertise to communicate with Center/Agency policies as related to the development of rare disease drugs.
- Mastery professional skills collaborating and facilitating with a variety of officials at various levels of authority from both public and private organizations including senior management officials, Center level officials, Office of the Commissioner, other FDA Centers, other federal agencies, Congress, the scientific/medical community, academia, and the regulated industry.

Qualifications:

Basic Qualification Requirements:

Education: A degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates.

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 internships, residency, and fellowship programs that are approved by accrediting bodies recognized within the US or Canada.

If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional 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 further information, visit the U.S. Department of Education website for Foreign Education Evaluation.***

How you will be Evaluated: You will be evaluated for this job based on how well you meet the qualifications above.

This is a Title 21 announcement: Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

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), SF50 (if applicable), copy of unofficial transcripts, latest PMAP (if applicable), and letter of interest with ***"CURES CBER/OCD* Associate *Director for Rare Diseases and Special Populations"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **September 20, 2024.**

Announcement Contact:

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

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FDA is an equal opportunity employer.