Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of the Center Director (OD)
Immediate Office of the Director (IOD)
Health Scientist Administrator (Jurisdiction)

Application Period: 3/31/2023 – 4/13/2023

Area of Consideration: HHS-Wide
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: Health Scientist Administrator (Jurisdiction)*
*Multiple selections can be made from this announcement

Series: 0401, 0403, 0405, 0601, 0602, 0858, 1320

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

Work Schedule: Full Time

Salary:
Series 0401, 0403, 0601, 0858, 1320 = Table 1: Starting at $132,368 and is set to commensurate with education and experience.
Series 0405 (Pharmacology) – Table 2: Starting at $132,368 and is set to commensurate with education and experience.
Series 0602 (Physician) – Table 3: Starting at $180,000 and is set to commensurate with education and experience.

Telework Eligible: Yes

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: 3591

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 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 is the federal agency responsible for protecting the public health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by helping to ensure the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. 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 public health through the regulation of biological and related products including blood, vaccines, allergenics, human tissues, and cellular and gene therapies. CBER protects and advances the public health by helping to ensure that biological products are safe, pure, and potent. CBER also provides the public with information to promote the safe and appropriate use of biological products.

Duties/Responsibilities - The incumbent serves as the Health Scientist Administrator for the Jurisdiction and Ombudsman Staff under the Immediate Office of the Director. This position reports to the Associate Director for Product Management. The incumbent serves as a health scientist administrator, center level product jurisdiction officer and combination product review liaison, establishing and representing CBER's position on the regulatory identity and assignment of medical products, assisting the offices with the combination product review process including the Intercenter consult process, as well as application of related jurisdiction and combination product policies.

The Health Scientist Administrator participates as a member of the CBER IOD senior staff, providing leadership and guidance in matters pertaining to product assignment and regulation, contributing to development of policy documents (e.g. guidance, regulation, internal standard operating procedures) related to combination products. The incumbent determines resolutions to address highly innovative technologies and cutting-edge science and policy issues concerning regulatory pathways and product labeling. The incumbent participates in the update of existing policies and contributes to development of new policies and procedures related to jurisdictional assignments and to the review of combination products in concert with the Office of Combination Products, counterparts in other medical product centers, and senior CBER management. These policies may be related, but are not limited to, the consultative and/or collaborative process used by the Centers, post-market regulation of products, resolution of disputes pertaining to CBER products, product cross-labeling, interpretation of legislative intent, inter-center agreements, primary mode of action analysis, and type(s) of marketing applications required.

Specifically, the Health Scientist Administrator will:

- Advise senior CBER managers about jurisdiction and combination product law, regulation, and policy. In doing so, the incumbent provides advice, guidance, and recommendations that reflect sound judgment and knowledge of current science and the applicable laws, regulations, and policies.
- Communicate new policies and programs to internal and external stakeholders. This may include training for FDA staff on process initiatives and new legislation related to combination products and jurisdictional assignments.
- Review, analyze, and respond within statutory timelines to jurisdictional assignment requests submitted by industry.
- Ensure that all issues presented by jurisdictional assignment requests are thoroughly analyzed, including assessment of the primary mode of action of the product, where applicable.
- Assume responsibility for ensuring that regulations and policies developed in the assignments are consistent with statutory requirements and existing policy, that their need is justified, and that adequate scientific and medical reviews have been completed by CBER to support the center position.
- Negotiate and facilitate during meetings which are frequently held with CBER staff, other affected Centers' staff, and Agency staff to make jurisdiction determinations and combination product policy.
- Advise CBER review staff on the consultative and/or collaborative cross-center review process to be followed by the Centers in conducting the pre-market and post-market review of products assigned to CBER.

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.
- 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.
- 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.

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 Requirement: Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: OPM Occupational Series Qualification Requirements

Desired Education: Our ideal candidate will have an M.S., M.D. and/or Ph.D. degree in a relevant area of science or medicine and sufficient training/experience to apply both scientific and regulatory expertise to identify and apply pertinent precedents, applicable statutes, regulations, and Agency policies to the evaluation of complex medical products.

Professional Experience: The incumbent is required to have a working knowledge of the PHS Act and Food Drug and Cosmetic Act, new and revised regulations, and Agency policies applicable to product jurisdiction and combination product regulation to complete the assigned duties. In order to contribute to the Center's position on a product jurisdiction matter, the incumbent must apply both scientific and regulatory expertise about pertinent precedents, applicable statutes, regulations, and Agency policies.

Desired Professional Experience: As combination products incorporate advanced technologies and novel combinations, classification, assignment and regulation of these products and their single entity components, has become increasingly complex. An advanced degree in a relevant area of science or medicine and the ability to comprehend scientific discourse in other related areas pertinent to medical product development is needed to address complex product jurisdiction assignments.

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 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

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/OD/IOD/Health Scientist Administrator"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **4/13/2023.**

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.