Title 21 Temporary Promotion/Detail Announcement NTE 120 Days (Reimbursable)
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)

Application Period: February 16 - March 2, 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: Regulatory Review Resolution Specialist (Center Ombudsman)

Series: 0301

Location(s): White Oak Campus, Silver Spring, MD. 24145-0031.

Salary: Starting at $132,368

Work Schedule: Full Time

Telework Eligible: Yes

Full Performance Band Level: Band D

Cures Band(s): Band D

Travel Requirements: Up to 25%

Bargaining Unit: 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 or Agency) 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 safe, and effective.

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, allergenics, 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.

Duties/Responsibilities

The incumbent serves as the Regulatory Review Resolution Specialist (Center Ombudsman) in the Immediate Office of the Center Director (IOD) and reports directly to the Center Director, CBER. The incumbent serves as the Ombudsman who acts as an independent mediator in disputes related to the regulated industry and CBER to resolve issues in a manner that is timely, fair, and impartial.

Specifically, the Regulatory Review Resolution Specialist (Center Ombudsman) will:

- Oversee functions related to the constructive resolution of disputed matters through various activities to include conducting the initial investigation of complaints, collecting and organizing relevant supporting documents, facilitating communication between involved parties, and managing documentation concerning the final dispute resolution decision as needed.
- Oversee the independent management of cases and other related activities including leading stakeholder outreach, administrative process management, and development, and contributing to the development and delivery of training related to the dispute resolution field and the Ombudsman role.
- Oversee the complaint process related to the CBER and FDA scientific, regulatory, and administrative decisions which impact the Agency's pending regulatory matters.
- Manage and participate in the initial triage and investigations to take steps toward resolving disagreements.
- Oversee the information-gathering, data collection, and fact-finding throughout multiple organizations with affected persons and groups both internal and external; the analysis and evaluation of information, data, and facts; the development of case histories; maintenance of a database of case histories and reports; and the providing of possible solutions and negotiations with involved parties to expeditiously resolve disagreements at the lowest level.
- Collaborate with other key Center staff during the Center regulatory decision-making process with a goal towards improving procedures and increasing public confidence in the safety, effectiveness, and quality of biological related products.
- Present and direct recommendations to the appropriate party, to include the Center Director, program directors, professional scientific personnel, industry officials, FDA representatives, and others in matters related to the resolution process emanating from the review of applications, enforcement actions, or other requests for assistance from industry stakeholders pursuing various actions by the Center.
- Lead JOS in assessing the quality and consistency of the Center policies and procedures through evaluation of input obtained from industry stakeholders engaged in the dispute resolution process and related engagements.
- Supervise evaluations and the analysis of proposed policies for consistency with statutory requirements and existing policy and if their need is justified.
- Serve as the CBER 513(g) Coordinator, who oversee the review and response to Section 513(g) submitted "Requests for Information under the Federal Food, Drug, and Cosmetic Act (FD&C Act)", related to the class in which a device has been classified or the requirements applicable to a device under the FD&C Act.

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.
- 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: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

Desired Education: Candidates would ideally have a graduate degree or higher (*i.e.*, Masters, J.D., Ph.D., and/or M.D.).

Desired Professional Experience:
- Mastery knowledge of policy related to the regulatory field, management of biological product issues, the Agency and Center laws, policies, regulations, strategic priorities, programs, and processes, scope of the CBER biological products, devices, and drugs, dispute resolution theory, methods, and practices, and various appeal mechanisms and processes within the Agency and Center.
- Mastery knowledge of the administrative process for the review of the CBER devices through the 513g process, the process, procedures, and administrative/legal support required to develop the Center specific policy in CBER, and more broadly applicable policy developed in collaboration with other medical product centers and offices.
- Ability to effectively deal with members of the regulated industry, other representatives, and other interested parties, in analyzing and presenting highly sensitive, controversial, and complex issues.
- Ability to accomplish work through working collaboratively with others at all levels within the Center and Agency, the regulated industry, and other organizations, both national and international, impacted by the Center to achieve appropriate and timely support, and to reconcile divergent viewpoints.

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.

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.

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), latest PMAP (if applicable), and letter of interest with ***"CURES CBER/IOD Regulatory Review Resolution Specialist (Center Ombudsman) – temp promo/detail"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **March 2, 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.

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