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 Compliance and Biologics Quality (OCBQ)
Division of Case Management (DCM)
Biological Drug and Device Compliance Branch (BDDCB)

Application Period: June 21, 2024 – July 5, 2024

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: Consumer Safety Officer*
*Multiple selections can be made from this announcement

Series: 0696

Location(s): White Oak Campus, Silver Spring, MD. 241450031

Salary: Starting at $117,962

Work Schedule: Full Time

Cures Band(s): Band C

Telework Eligible: Yes

Full Performance Band Level: Band C

Travel Requirements: Less than 25%

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 (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency that regulates human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices.

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 a Consumer Safety Officer in the Biological Drug and Device Compliance Branch (BDDCB) within the Division of Case Management (DCM) under the Office of Compliance and Biologics Quality (OCBQ) within CBER. The Consumer Safety Officer serves as a specialist and technical expert in compliance and enforcement with responsibility for the review and analysis of a variety of more complicated cases. The incumbent is responsible for managing a category or group of products that are distinctly more difficult to deal with because of the science and technology behind the regulated products. The Consumer Safety Officer reviews inspection reports submitted by field investigators to determine compliance with applicable laws and regulations.

Specifically, the Consumer Safety Officer will:

- Manage complex legal and regulatory issues based on advanced scientific education and/or long, practical experience in Agency regulatory and compliance processes.
- Perform the full range of compliance and enforcement actions; advisory, administrative, and judicial, including casework and related functional responsibilities in the area of biological drugs and devices.
- Coordinate and evaluate compliance review processes within CBER and across the Agency, draft or edit guidance documents involving Branch matters, mentor, and maintain standard operating policies and procedures regarding compliance and enforcement activities.
- Analyze and determine the adequacy of proposed compliance and enforcement actions by an FDA Center/Office regarding the compliance and enforcement of regulated products with the Federal Food, Drug, and Cosmetic Act.
- Determine if additional data or other information is necessary within the context of applicable laws, policies, regulations, and guidelines.
- Incumbent reviews inspection reports and evaluates the compliance status of licensed biological product manufacturers and is routinely assigned those manufacturers and facilities that involve unusual and/or intricate manufacturing processes and quality controls, and/or a wide variety of biological products.
- Incumbent evaluates Biological Product Deviation Reports from the manufacturers of biological drugs and devices regulated by CBER.
- Incumbent reviews proposed regulatory actions, providing recommendations and guidance to field compliance organizations, and the regulated industry, and representing the Center at local, State, and national meetings on matters concerning regulated products.
- Participate in internal and external meetings to formulate, develop, or explain policy for regulating biological drugs and CBER-regulated devices, advanced or specialized program concepts, accepted or recognized standards, or expertise in scientific or regulatory programs.
- Develop and recommend new and revised guidelines for regulated products and proposing areas of study for new or revised regulatory policy and guidelines.
- Monitor, evaluate, and make necessary recommendations for improvement based on routine surveillance activities, enforcement and compliance actions taken by BDDCB staff.
- Advise the Office Director, Division Director, and Branch Chief, regarding policy matters involving technical aspects of regulation of biological drugs and devices regulated by CBER.
- Lead, as appropriate, requests for advisory opinions for regulated industry, Congress, department officials etc. for the Branch.
- Mentor and develop training for other staff members in evaluating compliance issues for biological products.
- Perform other duties as assigned.

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 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.

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

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), latest PMAP (if applicable), copy of your unofficial transcripts, and letter of interest with "**CURES CBER/OCBQ/DCM/BDDCB/Consumer Safety Officer**" in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **7/5/2024**.

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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