Title 21 Vacancy Announcement
Consumer Safety Officer
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 Inspections and Surveillance (DIS)
Program Surveillance Branch (PSB)

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: The Public
Open & Close Dates: 11/04/2024 – 11/18/2024
Salary: Starting at $117,962 and is set to commensurate with education and experience
Band: C
Occupational Series: 0696
Duty Location: Silver Spring, MD
Remote Job: No
Telework Eligible: Yes
Travel Required: 25% or less
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band C
Supervisory Status: No
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 3591

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.

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

Duties:

The incumbent serves as a Consumer Safety Officer (CSO) in the Program Surveillance Branch (PSB) of the Division of Inspections and Surveillance (DIS) in the Office of Compliance and Biologics Quality (OCBQ). The Consumer Safety Officer is required to bring professional competence to bear in analyzing significant facts and developing logical conclusions regarding the regulation of biological products under Public Health Service Act and the federal regulations at Title 21, Code of Federal Regulations, Part 600 and part 1271, and Cosmetic Act and federal regulations relating to current good manufacturing practices (CGMP's) for finished pharmaceuticals and medical devices, as well as federal regulations relating to current good tissue practices (CGTP's).

Specifically, the Consumer Safety Officer will:

- Coordinate meetings and manage the process in the preparation of comprehensive surveillance and compliance programs.
- Participate in work groups in the preparation of guidance documents concerning inspectional procedures and compliance policies.
- Provide regulatory guidance to employees and investigators on compliance related issues regarding reporting requirements for biological products.
- Review regulatory reports to facilitate decision making processes.
- Assess biological product quality reports to determine appropriate follow-up which may involve recommending inspections or recommending products for possible recall classification.
- Prepare written annual summary regarding data collected from reports submitted to the Agency concerning licensed biological products.
- Develop the Agency position in response to requests or advisory opinions from the regulated industry, covering the full range of subject matter within the assigned work area.
- Discuss issues with scientific and medical personnel within FDA to establish precedents for action or to identify and recommend an FDA position when policy is nonexistent or not applicable.
- Draw conclusions and recommend a specific reply to inquiries, designating new policy interpretations and the need for new or revised policy developed by CBER.
- Serve as a contact point for inquiries from both CBER and investigators for guidance concerning appropriate actions against non-complying license and/or unlicensed biological product establishments in accordance with compliance programs and Agency/Center policy.
- Participate in meetings with CBER staff and management for the purpose of discussing and offering solutions to industry problems, trends, violations, and policy.

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.
- 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.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- 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.*

Qualifications:

Basic Qualification Requirements:

In order to qualify for this Title 21 (Cures) position, the candidate(s) must meet the following ***requirements:***

A. A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work.

The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.

OR

B. Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in paragraph A above, plus appropriate experience or additional education.

Desired Professional Experience/Qualifications:

The experiences and qualifications listed below are considered preferable/desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.

- Candidates must possess expertise in blood banking and transfusion medicine.
- Candidates must also have experience with policies and procedures regarding the safe use of blood and blood practices.

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.

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.

How to Apply:

Please submit **electronic resume or curriculum vitae** (for each position held, please be sure to clearly define the number of years by month and year, all completed trainings, and clearly describe duties and accomplishments). Please also submit **SF50 (if applicable)**, **latest PMAP (if applicable)**, **unofficial transcripts**, **Foreign Credit Evaluation (if applicable), copy of your active medical license/s (if applicable**), **copy of your board certification/s (if applicable)**, and **letter of interest (Word or PDF)** with ***"Title 21 CBER/OCBQ/DIS/PSB Consumer Safety Officer"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through 11/18/24.**

Announcement Contact:

For questions regarding this Title 21 (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.