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 Vaccines Research Review (OVRR)
Division of Clinical and Toxicology Review (DCTR)

Application Period: January 16, 2024 – February 16, 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: Associate Director of Labeling

Series: 0601 (General Health Scientist), 0602 (Physician)

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

Salary:
0601 (General Health Scientist) = Table 1: Starting at $139,395.
0602 (Physician) = Table 3: Starting at $180,000.

Work Schedule: Full-Time

Telework Eligible: Yes – as determined by agency policy.

Title 21 Band: D

Full Performance Band Level: D

Travel Requirements: 25% or less

Bargaining Unit: 8888

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 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.

The Office of Vaccines Research and Review (OVRR) protects and enhances public health by assuring those available vaccines, allergenic extracts, and related product are safe and effective.

The Division of Clinical and Toxicology Review (DCTR) directs and performs the review process for investigational new drug (IND) applications, biological license applications (BLAs), and amendments regarding biological drug products regulated by the Office. DCTR coordinates the processing of INDs and BLAs through the other Divisions within the Office and coordinates licensing activities among the Divisions. DCTR develops policies and procedures applicable to the review of preclinical information, clinical trial design, and data submitted in support of BLAs and INDs.

Duties/Responsibilities

The incumbent serves as the Associate Director of Labeling (ADL) for the Division of Clinical and Toxicology Review (DCTR) within the Office of Vaccines Research Review (OVRR). This position reports to the Deputy Director of the Division of Clinical and Toxicology Review. The ADL provides recommendations to the review team members and division management to ensure that the Prescribing Information (PI) meets requirements of statutes and regulations and is consistent, where appropriate, with FDA labeling guidance and CBER standards and policies.

The Associate Director of Labeling ensures that for health care practitioner use the PI conveys clear, concise, clinically meaningful, and scientifically accurate information, as determined by subject matter experts on the review team.

Specifically, the Associate Director of Labeling will:

- Review the PI at a high-level shortly after submission to identify any PI review issues and determine if the PI meets major regulatory requirements and the labeling review can begin.
- Recommend to the review team and management the PI review and alignment plan and ensure early and ongoing alignment between the PI text and each of the review disciplines (e.g., CMC, toxicology, clinical, etc.)
- Provide well-written and thorough comments and edits to the applicant-proposed PI prior to labeling meetings.
- Facilitate and lead labeling discussions during labeling meetings and provide cross-discipline labeling guidance.
- Manage and update PI edits and comments in the working version of the PI as they are addressed.
- Identify and resolve PI issues that arise both during and after labeling meetings.
- Coordinate and implement the review and development of pending labeling supplements (including PLR conversion and labeling supplements) and meet goals for timeliness.
- Compose and/or review labeling comments and recommendations before these are communicated to the applicant to ensure that the comments and recommendations do the following:
    - Provide appropriate rationale and, when applicable, reference applicable labeling regulations, statutes, and guidance (for substantive changes to applicant-proposed labeling).
    - Provide comments and recommendations that are well-formulated, coherent, and nonconflicting across disciplines.
    - Capture and reflect the core review team's integrated recommendations to the applicant.
    - Provide labeling expertise, review, and development for the PI submitted under Biologic License Applications (BLAs) and efficacy supplements (ESs) within the Office.
    - Complete labeling assignments within the prescription drug review division according to the Prescription Drug User Fee Act (PDUFA) performance goals (e.g., 6-, 8-, 10-, and 12-month review timelines) and the 21st Century Review process.
- Train members of the review team (e.g., staff involved in labeling review and development of review division products) on good labeling practices such as version control, early labeling review, information requests to applicants, including rationale for suggested labeling changes, and consistency of labeling across products, as applicable.
- Mentor review teams on labeling regulations, guidance documents, and policies that are applicable to the drug and biological product portfolio within the division.
- Brief the Division Director or delegate on all CBER labeling policies.
- Meet with the Division Director or delegate on significant issues related to labeling.
- Keep the Division Director or delegate and signatory (or signatory's designee) apprised of the progress of labeling review and development, including labeling issues, early and throughout the review cycle.
- Contact and collaborate with Division Director or delegate, as needed, to reach alignment on complex labeling issues, on cases lacking policy or precedent, and/or when the prescription drug review division believes that a given scenario warrants departure from existing FDA guidance and CBER standards and policies.
- Work cooperatively with the Regulatory Project Management (RPM) staff and discipline review teams to address issues and resolve conflicts that arise within and across disciplines to ensure efficient and timely labeling reviews.
- In conjunction with RPM staff, monitor the progress of discipline review and development of discipline-related parts of the PI.
- Assist in and provide oversight of the RPM's finalization of the PI and ensure that the finalized PI meets labeling format requirements and is consistent with format recommendations before application approval and sign-off.
- Ensure, in collaboration with core discipline reviewers, that the rationale for major changes to discipline-related portions of the applicant-proposed PI is adequately documented in the official archive system.
- Contribute to a high-level summary of labeling considerations for the application review as determined by the core review team (e.g., author the labeling section of the Integrated Review Template, as appropriate).
- Participate in after-action reviews and continuous improvement activities to enhance the efficiency and effectiveness of future PI reviews within the Office.

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 supervisory 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 Title 21 (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 Title 21 appointments. The FDA OTS will use the basic requirements defined in the respective OPM Qualification Standards or below Education/Graduate Training requirements 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/Graduate Training Requirements:

0601 Series (General Health Scientist)

Candidates must possess the required OPM individual occupational requirements to qualify for the appropriate series applicable to the position.

Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

0602 Series (Physician)

Education: A degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent.

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 internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the United States or Canada.

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.

Desired Education: For 0601 series, candidates would ideally have a MD, PhD, or BSN.

Desired Professional Experience:

- Excellent written communication skills, including the ability to: develop new labeling sections (e.g., develop a new WARNING AND PRECAUTION section); communicate labeling issues to division management and members of the review team; and communicate labeling issues to applicants.
- Excellent oral communication skills to convey the major labeling issues to the Division Director (supervisor), team leaders, additional CBER review team members, applicants, and if applicable, the Office Director and Center Director
- Possesses the in-depth experience needed to ensure labeling is interpretable by healthcare practitioners by creating tables, figures, and bulleted lists; using consistent terminology throughout the labeling when scientifically valid; distributing information into the appropriate section of the labeling.
- Mastered knowledge of the 2006 Physician Labeling Rule, PLR regulations [21 CFR 201.56(d) and 21 CFR 201.57], and non-PLR "old format" regulations [21 CFR 201.56(e) and 21 CFR 201.80] regarding the format and content of the PI; the labeling resources on the FDA's Labeling Resources for Prescription Drugs website; and the Selected Requirements of Prescribing Information (SRPI) review (a checklist of important format PI items based on labeling regulations and guidance).
- Mastered knowledge of the following, as it applies to labeling: the diseases and conditions for which the Office regulates drug and biologic treatments for; the clinically related (including pregnancy, lactation, females and males of reproductive potential, pediatric, and geriatric information), clinical pharmacology-related, pharmacology/toxicology-related, and chemistry-related information in the PI; the safety and efficacy of drugs and biological products in the review division portfolio; general principles of chemistry, biology, pharmacology and toxicology, clinical immunology and pharmacology, and statistics..
- Possesses a comprehensive understanding of important drug and biologic product development and labeling concepts including, but not limited to: clinical trial design; how to organize complicated dosage information (e.g., by using tables, organizing by subsections) in labeling; adverse event causality assessment; reasons to include adverse reactions in the WARNINGS AND PRECAUTIONS section; how to distribute drug interaction information throughout the labeling (e.g., DOSAGE AND ADMINISTRATION, WARNINGS AND PRECAUTIONS, DRUG INTERACTIONS, and CLINICAL PHARMACOLOGY sections); reasons to pool safety data from multiple studies; and reasons to include or not include clinical studies in the CLINICAL STUDIES section of the labeling.

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), unofficial transcripts and letter of interest with ***"CURES CBER/OVRR/DCTR Associate Director of Labeling"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through February 16, 2024.

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.