Title 21 Vacancy Announcement
Associate Director for Labeling
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Therapeutic Products (OTP)
Office of Clinical Evaluation (OCE)
Immediate Office of the Director (IOD)

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: FDA-Wide *Multiple selections can be made from this announcement.
Open & Close Dates: 1/8/2025 – 1/18/2025
Salary: Table 1: Starting at $139,395.00 and is set to commensurate with education and experience.
Band: D
Occupational Series: 0601 (General Health Scientist)
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 D
Supervisory Status: No
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 8888

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 the Associate Director for Labeling (ADL) within the Office of Clinical Evaluation (OCE) under the Office of Therapeutic Products (OTP), reporting directly to the OCE Office Director. In this role, the ADL advises the review team and Office management to ensure that the Prescribing Information (PI) complies with statutory and regulatory requirements and aligns, when appropriate, with FDA labeling guidance and CBER standards and policies. The ADL ensures that the PI provides healthcare practitioners with clear, concise, clinically relevant, and scientifically accurate information, as determined by the subject matter experts on the review team. The incumbent reviews the PI at a high level shortly after submission to identify any PI review issues and determine if the PI meets major regulatory requirements, allowing the labeling review to begin.

Specifically, the Associate Director for 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, allowing the labeling review to begin.
- Recommend to the review team and management the PI review and alignment plan, ensuring 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, offering 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) while meeting timeliness goals.
- Compose and/or review labeling comments and recommendations before communicating them to the applicant to ensure that they:
    - Provide appropriate rationale and, when applicable, reference labeling regulations, statutes, and guidance (for substantive changes to applicant-proposed labeling).
    - Ensure comments and recommendations 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 products regulated by OCE) on good labeling practices such as version control, early labeling review, information requests to applicants, rationale for suggested labeling changes, and consistency of labeling across products, as applicable.
- Mentor review teams on labeling regulations, guidance documents, and policies applicable to the drug and biological product portfolio within the Office.
- Brief the Office Director or delegate on all CBER labeling policies.
- Meet with the Office Director or delegate on significant issues related to labeling.

- Keep the Office 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 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 and provide oversight during RPM's finalization of the PI and ensure 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.

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.
- 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.
- 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:***

- 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.

Desired Professional Experience/Qualifications:

- 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.

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/OTP/OCE/IOD Associate Director for Labeling*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through January 18, 2025.**

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.