Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Surveillance and Epidemiology (OSE)

Application Period: February 17, 2023 - March 10, 2023

Area of Consideration: Open to current OSE employees. Must be currently employed by the Food & Drug Administration, serving on an appointment in the excepted or competitive service. Commissioned Corp employees may apply. **Please see below criteria**

Position: Associate Director for Nomenclature & Labeling, DMEPA I

Series: AD-0601

Location(s): Silver Spring, MD

Salary: Starting at $155,700

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Bargaining Unit: 8888

Relocation Expenses Reimbursement: Will NOT be paid

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) 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, are safe and effective.

The Center for Drug Evaluation and Research (CDER), is responsible for regulating prescription drugs, including new drugs, generic drugs, biological products and biosimilars as well as over- the-counter drugs (OTC). CDER's drug regulatory responsibilities include

premarket review of new drugs and generic drugs; maintenance of the OTC drug monograph system; monitoring of all marketed drug safety and promotional activities; review, monitoring and enforcement of drug quality during the entire drug life cycle; and ensuring drug products in the market comply with the law.

The Office of Surveillance and Epidemiology (OSE) within the Center for Drug Evaluation and Research (CDER) works to detect, assess, prevent, and manage the risks of medications so that they can be relied upon to treat disease and improve health. All medicines have risks as well as benefits; the risks of medicines are the chances that something unwanted or unexpected could happen when consumers use them. OSE participates in the safety analysis of drugs before they are marketed to patients and consumers.

The Division of Medication Error Prevention and Analysis I (DMEPA I) is responsible for the premarket review of proposed proprietary medication names, labels/labeling, packaging, product design and Human Factor Studies to identify, evaluate, and minimize the potential for medication errors and use errors for CDER-regulated products.

This position is located in the Division of Medication Error Prevention and Analysis I (DMEPA I), Office of Medication Error Prevention and Risk Management (OMEPRM), Office of Surveillance and Epidemiology (OSE), CDER.

Duties/Responsibilities

As the **Associate Director for Nomenclature & Labeling**, the incumbent serves as a senior advisor to the Division Director and Deputy Director on complex scientific, administrative, procedural, and policy issues that are related to the nomenclature, labeling, and packaging of medical products that are important to advancing the programmatic goals.

- Provides day to day management, oversight, and direction to staff involved in the evaluation of proposed proprietary names (nomenclature), labeling, and packaging.
- Plans, manages, organizes, and directs pre-market and post-market operations, programs, functions, and activities of the Division related to the nomenclature, labeling, and packaging design of medical products to prevent medication errors.
- Serves as an advisor on complex drug safety-related issues and activities related to the nomenclature, labeling, and packaging of medical products to Division and Office staff and other Center-wide programs
- Represents the Division and Office in negotiating with internal and external stakeholders, including those representing organizations such as Congress, other Federal agencies (e.g., Emergency Management Agency), State, local, and foreign government (e.g., Health Canada), the regulated industry, professional and industry organizations, patient safety organizations, and public interest groups.
- Presents expertise on complex scientific and regulatory issues related to the nomenclature, labeling, and packaging of medical products to internal (e.g., CDER senior leadership) and external (e.g., for example regulated industry or at professional meetings and conferences) stakeholders.
- Directs and/or delegates the preparation of written reviews related to nomenclature, labeling, and packaging designs of medical products that are evaluated by DMEPA I.

Supervisory Responsibilities: N/A

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.

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:
Associate Director for Nomenclature and Labeling, AD-0601 Series:
Minimum Education Requirement: Meets the Office of Personnel Management (OPM) Individual Requirements (IOR) for General Health Series (0601)

Desired Education:

Our ideal candidate will possess:

A 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 (https://www.ed.gov/) at the time the degree was obtained.

Professional Experience:
Our ideal candidate will possess:

- Expert knowledge of the Food, Drug and Cosmetic (FD&C) Act, Code of Federal Regulations and other Agency Guidelines and policies pertaining to review of drug and therapeutic biologic applications.
- Skill in applying expertise in advanced professional theories, principles, concepts, standards, and methods of pharmacy and/or drug regulatory process sufficient to serve as expert to resolve difficult problems and issues, as well as plan, design, monitor and evaluate complex projects.
- Ability to interpret and apply appropriate guidelines to address pre and post marketing drug safety.
- Demonstrated ability and experience to develop networks and build alliances; collaborate across boundaries to build strategic relationships and achieve common goals.
- Healthcare professional licensure (e.g., MD, DO, PharmD, Nurse Practitioner (NP), Physician's Assistant (PA)

Desired Professional Experience: Our ideal candidate will possess extensive drug safety experience.

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: Non-Sensitive/High Risk

If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later. Applicants are also advised that all

information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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.

How to Apply

Submit resume, cover letter, and supervisory concurrence by **March 09, 2023** to: OSE-PMAS-Admin-Team@fda.hhs.gov Candidate resumes may be shared with hiring official within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions, please contact OSE-PMAS-Admin-Team@fda.hhs.gov.
Please reference **Job Reference ID: ADNLDMEPAI23**.

Announcement Contact

For questions regarding this Cures position, please contact OSE-PMAS-Admin-Team@fda.hhs.gov.

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