Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of New Drugs (OND)
Office of Nonprescription Drugs (ONPD)
Division of Nonprescription Drugs II (DNPD2)

Application Period: December 09, 2024 – December 20, 2024

Area of Consideration: 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: Social Science Analyst

Series: AD-0101

Location(s): Silver Spring, MD

Work Schedule: Full-Time

Salary: Starting at $139,395

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: 3591

Relocation Expenses Reimbursement: You WILL NOT qualify for reimbursement of relocation expenses in accordance with agency policy.

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 safe, and effective.

The mission of the Center for Drug Evaluation and Research (CDER) is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates nonprescription/over-the-counter (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The Office of New Drugs (OND) is a super office within CDER responsible for the assessment of new drugs and therapeutic biologics. OND provides clinical, nonclinical, and regulatory expertise on the full range of drugs and therapeutic biologics that can be made available to the American people.

The Office of Nonprescription Drugs (ONPD) consists of two review divisions: The Division of Nonprescription Drugs I and II. The ONPD oversees the development, review, and regulation of nonprescription products (marketed under OTC monographs and under NDAs) reviewed in these divisions.

The Divisions of Nonprescription Drugs I and II (DNPD I-II) coordinate, review, and decide on the appropriate action for all New Drug Applications (NDAs), for all Over the Counter (OTC) drug monographs, and Investigational New Drug (IND) submissions for nonprescription drug products. The DNPD I-II develop and implement standards for the safety and effectiveness of nonprescription drug products, as well as develops the scientific basis for rulemaking regarding the regulation of OTC monograph drugs. The mission of the DNPD I-II is to protect the public health by ensuring the safety, efficacy, and security of nonprescription products for human use.

Duties/Responsibilities

As a **Social Science Analyst**, the incumbent provides technical and regulatory expertise.

- Reviews and evaluates a variety of complex label comprehension studies, self-selection studies, and actual use protocols to determine if they are well-designed and adhere to over-the-counter (OTC) regulations.
- Reviews and provides advice to stakeholders (including FDA decision-makers, medical product sponsors and instrument developers) on label comprehension studies, self-selection studies, and actual use studies used in OTC drug product development collaboratively as part of a multidisciplinary team inclusive of clinical and biostatistical experts.
- Reviews and performs in-depth analysis of data from label comprehension studies to determine whether average and low literacy consumers, and other sub-groups, adequately understand the information on the tested Drug Facts label(s).
- Acts as primary liaison with critical persons and groups both inside and outside of the

agency and provides expert consultation and advice. The incumbent collaborates closely with interdisciplinary scientists and the medical officers/physicians in the Division to be certain that the label contains all relevant medical information necessary to insure the safe and effective use of the product and follows the Drug Facts Format.

- Participates in the development of communication tools to address study endpoints issues and develops and assesses new communication tools. Further, the incumbent contributes to the development and design of the language for prescription-to-OTC switch product labels so that these labels clearly communicate the information that consumers must understand to properly use OTC products and collaborates with colleagues within the Division, Office and the Center for Drug Evaluation and Research to apply novel and state-of-the-art information and insights from the social science research literature to government policy decision-making and communications.
- Collaborates with internal and external stakeholders to apply current information and insights from social science and measurement research to advance government policy decision-making and communication as related to study endpoints and leads the writing of Guidance for Industry that address social science issues that pertain to the OTC drug development process.
- Reviews and analyzes data from self-selection studies to determine if normal and low literacy and other relevant sub-groups can appropriately self-select to use the drug product.
- Reviews and analyzes data from actual use studies to determine whether consumers are likely to use the OTC drug product appropriately in the OTC setting. This work is performed in collaboration with Physicians/ Medical Officers in the Division.
- Provides responses to press and Congressional inquiries related to nonprescription drugs marked or to-be-marked under approved NDAs and inquiries related to OTC monographs.
- Reviews and analyzes labeling language related to OTC drug monographs. Collaborates with other staff scientific personnel who are developing OTC drug monographs to be certain that the labels are complete regarding medical content and consistent in content and format with the Federal Regulations. Works with other members of the Division to create package inserts that consumers can easily understand.
- Presents data on label comprehension, self-selection, and actual use studies at Nonprescription Drug Advisory Committee Meetings. Solicits and nominates candidates for the Nonprescription Drug Advisory Committee (NDAC) and advises Division management on topics to be discussed with the NDAC.

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.

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:

Social Science, AD-0101 Series

Degree: behavioral or social science; or related disciplines appropriate to the position.

OR

Combination of education and experience that provided the applicant with knowledge of one or more of the behavioral or social sciences equivalent to a major in the field.

OR

Four years of appropriate experience that demonstrated that the applicant has acquired knowledge of one or more of the behavioral or social sciences equivalent to a major in the field.

For more information, please see: OPM Occupational Series Qualification Requirements.

Desired Education, Experience, Professional Experience:
Our ideal candidate will possess:

- Expertise in reviewing policy documents with significant underlying scientific issues, and decision memoranda, to ensure that they are comprehensive, accurate, and consistent with the Administration and Department policy.
- Effective and experienced communicator who can explain, advocate and express facts and ideas in a convincing manner and negotiate with individuals and groups internally and externally, as appropriate.
- Familiar with and able to clearly communicate current information and insights from social science, measurement, and study endpoint research to the advancement government policy, decision making and communication.
- Expertise on the development and validation of clinical outcome assessments (COAs); provides expert advice grounded in experience and the scientific literature to stakeholders on how to develop COAs and the methods employed to demonstrate validity for use in regulatory decision-making.
- Experience that enables the incumbent to evaluate a variety of complex study endpoint issues to support labeling claims including the evaluation of treatment in clinical trials and the evaluation of label comprehension studies, self-selection studies, and actual use studies.
- Collaboration and critical-thinking skills that enable the incumbent to effectively collaborate with Medical Officers and other relevant content disciplines, intra-organizational levels and other interorganizational participants in the approval process to ensure that all relevant matters are addressed in relation to study endpoint issues.
- A strong candidate can readily demonstrate advanced critical thinking and communication skills.

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 Recognition of Foreign Qualifications | International Affairs Office (ed.gov)

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/Moderate Risk

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 the 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.

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

Equal Employment Opportunity Policy

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

Reasonable Accommodation Policy

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

Submit resume with cover letter and unofficial transcripts by **December 20, 2024**, to Sabrina Smith at ONDIORecruitment@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'.

Please reference **Job Reference ID: PD-24-064** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Sabrina Smith at Sabrina.Smith@fda.hhs.gov.

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