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)
The Office of Nonprescription Drugs (ONPD)
The Divisions of Nonprescription Drugs I and II (DNPD I-II)

Application Period: November 25, 2024 – December 27, 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:
$82,764 – $109,506 (Band A)
$99,200 – $133,845 (Band B)
$117,962 – $164,260 (Band C)

Cures Band(s): Band A/B/C

Full Performance Band Level: Band C

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 over-the-counter (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The Office of New Drugs (OND) is a super office within the Center for Drug Evaluation and Research 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 is responsible for evaluating 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. Under direction from the supervisor, the incumbent will review and provide 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 nonprescription product development collaboratively as part of a multidisciplinary team inclusive of clinical, interdisciplinary scientist, and biostatistical experts.

Band A:

- Evaluating 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.
- Review and provide 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 nonprescription product development collaboratively as part of a multidisciplinary team inclusive of clinical, interdisciplinary scientist, and biostatistical experts.

- Analyze data from label comprehension studies to determine if the studies were well-designed and conducted and whether average and limited literacy consumers, and other relevant sub-groups adequately understand the information on the tested Drug Facts label(s). These studies are broad in scope and affect a significant portion of regulated industry, as well as the public.
- Responsibilities are applied by Social Science Analyst across ONPD, but with some variation depending on the ONPD staff to which the Social Science Analyst is assigned.

Band B

- Meet duties and responsibilities outlined in Band A above
- Advises stakeholders (including FDA decision-makers, medical product sponsors and instrument developers) on label comprehension studies, self-selection studies, and actual use studies used in nonprescription drug product development collaboratively as part of a multidisciplinary team inclusive of clinical experts, interdisciplinary scientists and biostatistical experts.
- Analyzes data from label comprehension studies to determine whether the studies were well-designed and conducted and whether average and limited literacy consumers, and other relevant sub-groups, adequately understand the information on the tested Drug Facts label(s). These studies are broad in scope and affect a significant portion of regulated industry, as well as the general public.
- Analyzes data from self-selection studies to determine if the studies were well-designed and conducted and whether normal and limited literacy and other relevant sub-groups can appropriately decide whether to use the drug product.
- Analyzes data from actual use studies to determine whether consumers are likely to use the OTC drug product appropriately in the nonprescription setting without a healthcare provider's supervision.
- Collaborates with other scientific personnel, including clinical reviewers from the nonprescription and prescription divisions, interdisciplinary scientists, statisticians, clinical team leader, Deputy Division Director, Division Director, and the Associate Director for Monographs.

Band C

- Meet duties and responsibilities outlined in Bands A and B above.
- Advises on complex and precedent-setting policy and program issues, developing policies, strategies, and plans for Social Science analysis programs/projects for agency-wide application.
- Collaborates with interdisciplinary scientists and physicians to review and analyze data from actual use studies to determine whether consumers are likely to use the OTC drug product appropriately in the OTC setting without the supervision of a healthcare professional.

- Analyzes data from self-selection studies to determine if average consumers and other relevant sub-groups can appropriately decide if they should use the drug product. These studies are broad in scope and affect a significant portion of regulated industry, as well as the general public.

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.
- 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:

General Social Science, AD-0101 Series:

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

Desired Professional Experience:
Our ideal candidate will possess:

- Makes decisions regarding application of individual procedures for scientific, technical, or professional tasks requiring innovative approaches.
- Coordinates own work with the work of other technical contributors to ensure successful completion of assigned tasks.
- Provides subject matter expertise on identifying risks to quality of activity outputs.

Desired Skills, Experience, or Education:
Our ideal candidate will possess:

Band A:

- Knowledge of social science research or drug development
- Ability to assist in performing and/or analyzing clinical research or social science research.
- Knowledge of basic statistical principals to support decisions regarding drug product labels.
- Basic knowledge and understanding of FDA's mission and scope.

Band B:

- Experience in problem-solving techniques, which include identifying problems, gathering information, drawing conclusions, recommending solutions, as well as negotiating acceptance and implementation of recommendations.
- Experience utilizing oral communication techniques to present findings or recommendations.
- Experience in interacting with diverse audiences, including establishing and maintaining effective relationships with customers, information sources, and multi-disciplinary team members.

Band C:

- Competitive candidates will have a relevant doctoral degree (e.g., health services or health outcomes research, biostatistics, educational research, public health/epidemiology, pharmacy, medicine, osteopathy, behavioral/social science research) and strong critical thinking and communication skills.
- Demonstrated experience utilizing oral communication techniques to present findings or recommendations.

- Demonstrated experience utilizing written communication techniques to preparing scientific papers or generate reports.

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 (Band A/B/C)

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 actions.

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 or curriculum vitae with cover letter to OND-Employment@fda.hhs.gov by **December 27, 2024.** Candidate resumes may be shared with hiring officials within the Center for Drug Evaluation and Research with similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference **Job Reference Source Code ID: 25-004EG** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact OND’s Admin Analysis Staff at OND-Employment@fda.hhs.gov.

The Department of Health and Human Services is an equal opportunity employer with a smoke

free environment.

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