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 Surveillance and Epidemiology (OSE)
Office of Pharmacovigilance and Epidemiology (OPE)
Division of Epidemiology I or II

Position: Epidemiologist

Series: AD-0601

Location(s): Silver Spring, Maryland

Travel Requirements: 10% or less

Application Period: November 30, 2020 – December 11, 2020

Salary: Starting at $102,662 (Cures Band C)

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

Special Notes: This position is being filled under an excepted 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 the authority. Additional information on 21st Century Cures Act can be found here.

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 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.

This position is in the Divisions of Epidemiology (DEPI I and II), Office of Pharmacovigilance and Epidemiology (OPE), Office of Surveillance and Epidemiology (OSE), CDER. The mission of the divisions is to protect the public using epidemiologic evidence to assess the safety and effectiveness of drugs and biologics and evaluate observational methods and analytical approaches of real-world evidence for drug efficacy. The divisions in collaboration with other disciplines, accomplish this by detecting, assessing, and evaluating safety signals of drugs and biologics; conducting and evaluating drug and biologic safety and effectiveness surveillance research using the best available epidemiologic methodologies across OSE and CDER.

Position Summary:

The incumbent will be responsible for providing regulatory expertise in the use of various data sources and methodologies to assess and inform drug safety and the observational aspects of drug efficacy/effectiveness evaluations. Data evaluated by the divisions may include evidence generated from clinical trials data as well as evidence generated from non-randomized studies including observational studies using various population sources and study designs.

Duties/Responsibilities:

- Provides expertise in the use of data such as computerized electronic medical records, claims, managed care data, as well as other data sources such as prospective data collection to conduct epidemiologic evaluations
- Coordinates and conducts epidemiologic analyses and reviews required for the assessment of the safety and efficacy/effectiveness of medical products for use in the United States; efforts include specification of regulatory research questions, selection of adequate population or data sources to inform regulatory questions, implementation of data management strategies and preparation of analytical datasets, development and implementation of appropriate study, design and analytical methodologies, and provision of adequate interpretation of results considering the strength of evidence to inform regulatory recommendations
- Provides technical assistance and participates fully in the scientific review of new drug and biologic applications when safety concerns are identified, or epidemiologic

expertise is needed; provides an evaluation of the advantages and limitations of utilizing observational population/data sources, study designs, and analytical strategies to evaluate safety concerns post-marketing, provides required assessments for issuance of post-marketing studies under the Food and Drug Administration Amendments Act (FDAAA); provides scientific and technical assistance in the development of drug specific post market safety surveillance plans, post-marketing requirements or post-marketing commitments

- Coordinates and conducts epidemiological and statistical studies in drug safety and effectiveness, conducting and coordinating safety surveillance, signal evaluation, and risk assessment of pharmaceutical products using epidemiologic approaches
- Provides technical assistance to other professionals in the organization on the use of complex statistical and epidemiologic methodologies to monitor and evaluate post-marketing drug safety issues and for the epidemiologic aspects of efficacy submissions utilizing real world data or relying on real world evidence; examines reports and articles prepared by others within the organization as part of the peer review process; serves as technical expert in study design, analytical methodologies utilized and interpretation of epidemiologic studies.
- Maintains contact with consumers of work products, usually professional personnel of government and non-governmental organizations; shares scientific findings of epidemiologic assessments at CDER briefings, other internal meetings and with external groups such as professional societies, presents review findings and provides scientific advice at Sponsor or Industry meetings, FDA advisory committee and professional meetings and conferences where the subject under consideration is concerned with the projects assigned to the incumbent; prepares manuscripts for submission and publication
- Prepares comprehensive reports of study protocols and results. These include discussion of the research objectives, assessment of the adequacy and validity of the data used in the analyses, assessment of the methodologies, results, and the regulatory and public health relevance of the findings; disseminates results of research projects in a wide range of venues including publications, peer-reviewed journals, summaries, manuscripts, and special reports. Presents results to the scientific community at professional meetings and conferences.

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. Click here to find out additional information about the Equal Employment Opportunity (EEO) for federal employees & job applicants.

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.

Professional Experience/Desirable Qualifications:

Key requirements will include:

- Possession of post-graduate epidemiology training and relevant epidemiology research experience
- Knowledge of multiple and appropriate data sources for drug safety assessment and the conduct of observational pharmacoepidologic studies
- Knowledge of Federal laws and FDA regulations and related guidances for industry including regulations pertaining to the legal and ethical conduct of human subjects research; and strong analytical, negotiation, and communication (writing and oral) skills
- Demonstrated leadership, interpersonal skills and knowledge of the many scientific areas important to postmarketing safety

Desirable Education:

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.

Conditions of Employment:

1. **Security Clearance:**

This position requires a Public Trust security clearance and the incumbent has access to sensitive, proprietary, or financial information.

2. **Ethics Requirements**:

This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

3. **How to Apply:**

Submit resume or curriculum vitae with cover letter by December 11, 2020 to: David Moeny David.Moeny@fda.hhs.gov or Simone Pinheiro Simone.Pinheiro@fda.hhs.gov. Candidate resumes may be shared with the hiring official in the Center for Drug Evaluation and Research (CDER) with a similar job vacany. Candidates can opt out of this process by annotating resume with "do not share." For questions please contact David.Moeny@fda.hhs.gov or Simone.Pinheiro@fda.hhs.gov.

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

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