TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Division of Pharmacology and Toxicology
Office of New Drugs

Position: Non-Clinical Reviewer

Series: AD-0601

Location(s): Silver Spring, MD

Travel Requirements: None

Application Period: 4/27/20 to 7/27/20

Salary: Starting at $102,663 (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 or Agency) 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 and prescription drugs, including biological therapeutics and generic drugs. The Office of New Drugs's (OND) public health mission is to protect and enhance the health of the public through the review and evaluation of scientific data submitted by pharmaceutical manufactures in support of New Drug and Investigational New Drug applications (NDA/IND), and to determine if candidate drugs are safe and effective.

Position Summary:

The Non-Clinical Reviewer is responsible for reviewing and evaluating the results of non-clinical pharmacologic, toxicologic, and pharmacokinetic studies submitted in support of INDs, NDAs, and Biological License Applications (BLAs); these studies assess drug safety based on studies conducted by the drug developer. Review of the non-clinical pharmacologic and toxicologic data includes evaluation of the quality and adequacy of the various assessments and studies, in addition to other aspects. These reviews serve as the basis for calculating initial safe starting doses in clinical trials, doses for longer duration clinical trials, and for product labeling (the package insert). Non-Clinical Reviewers prepare a comprehensive review of the data and submit recommendations and conclusions for consideration of the review team. As a Non-Clinical Reviewer, you will have the opportunity to:

- Advance the public health through new drug development;
- Experience teaching and training opportunities;
- Interact with pharmaceutical companies; and
- Work with a wide range of scientific disciplines in a team-oriented atmosphere

Supervisory responsibilities: None

Duties/Responsibilities:

The Non-clinical Reviewer reviews in silico, in vitro, ex-vivo and animal data submitted to Investigational New Drug Applications (INDs), New Drug Applications (NDAs), and Biological Licence Applications (BLAs), mechanism of action (MOA) as proof-of-activity for use of medicinal products in patients, and the safety of medicinal products for use in patients and healthy subjects to evaluate:

- Non-clinical data to recommend a first-in-human (FIH) dose range that is safe within the clinical trial context and therapeutic in patients (i.e. human dose selection involves employing advanced scientific knowledge that integrates medicinal products' pharmacology, molecular and cellular biology, systems biology, and safety profile. Mathematical modeling may be employed for human dose selection, as needed). Communicates his/her conclusion on the FIH dose range and the clinical limit dose to

the multidisciplinary review team and proposes clinical safety monitoring based on non-clinical data.

- Plan and carry out the assignment, resolving most of the conflicts that arise, coordinating the work with others as necessary, and interprets policy on own initiative in terms of established objectives. Determines the approach to be taken and the methodology to be used, and keeps the supervisor informed of progress and potentially controversial matters.

- Working as part of a multidisciplinary team, reviews non-clinical data throughout the drug development process and communicates any new safety findings to the FDA review team, in a formal or informal format, as needed. Evaluates specilized non-clinical studies such as animal efficacy studies via the Animal Rule for medical countermeasures, as needed.

- Develops a comprehensive summary and integrated evaluation of the non-clinical data submitted in INDs (and amendments), NDAs, and BLAs (and supplements), and prepares for supervisory concurrence. Determines other available information relevant to the assessment (e.g. published literature, genomic and other databases, quantitative structure-activity relationship) is incorporated into the evaluation, as appropriate. Conclusions of the Non-clinical Reviewer are integrated with the conclusions of other team members. He/she makes a determination as to whether the non-clinical studies support continued drug development in the patient population being studied.

- Evaluates whether non-clinical sections of product labeling have accurate and adequate information to communicate the safety and risks of use to patients. Information in the product labeling to be evaluated include, but are not limited to, genotoxicity, carcinogenicity, and reproductive safety (fertility, embryofetal, and postnatal development) of the drug, and duration of contraception where applicable. Collaborates with other Divisions or Offices and Centers, as appropriate.

- Meets with industry representatives to exchange information and to provide advice and guidance regarding those aspects of the application, notice, amendment, supplement, or report which fall within this area of review, with emphasis on deficiencies in animal studies, and discuss non-clinical studies needed in support of INDs, NDAs, or BLAs and to provide advice and guidance for product development regarding those aspects of the application that are within the area of activity/proof-of-concept, animal studies, and safety assessment.

- Makes regulatory recommendations, such as clinical hold (INDs) and drug approval (NDAs/BLAs) decisions, based on non-clinical data. In making regulatory decisions and

providing internal and external recommendations, the Non-clinical Reviewer follows FDA and ICH guidance documents and internal practices and policies, and thus he/she has knowledge of disease-specific, non-clinical, and mutli-disciplinary guidance documents.

- Attends meetings, conferences, and symposia of scientific organizations to remain aware and gain an understanding of developments in the field, to exchange ideas with scientific peers engaged in related areas, and to acquire information pertinent to the conduct of Divisional responsibilities. Attends courses related to the development of medicinal products. Serves as a CDER resource for non-clinical safety assessment by participating in specialized working groups or subcommittees.

- Maintains expert knowledge and keeps abreast of new findings by reading relevant scientific literature, current trends in disease-specific publications, therapeutics involved within his or her Division, and new FDA and ICH Guidance documents and by participating in professional meetings, to keep abreast of current trends relative to work assignments. Participate in Divisional research projects, including issuance of Division-specific guidance and publishing articles in professional journals.

- Prepares a comprehensive summary of the data reviewed and submits substantive recommendations and conclusions for approval by Supervisory. Based upon the findings in such reviews, the Non-clinical Reviewer determines whether: (1) the data are adequate; (2) the potential for risk is high or low; and (3) the data supports safety for the recommended use at the recommended dose and labeling.

- Performs other specialized duties related to safety assessment of medicinal products and their composition as assigned.

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 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.

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 (external link) at the time the degree was obtained.

Specialized Experience:

- Skill in applying expertise in advanced professional theories, principles, concepts, standards, and methods sufficient to conceive and apply experimental theories and new development applications
- Ability to extend and modify theories, concepts, and assumptions; resolve unique or novel problems, conditions, and issues; and significantly alter standard practices, equipment, devices, processes, and known techniques.
- Knowledge of current primary skills of occupational specialty, broad operating programs to advise senior colleagues and agency officials, and manages significant projects that represent an important segment of the agency's operating programs.

- Mastery knowledge of scientific methods and techniques related to the non-clinical data, pertinent laws, regulations, and Agency policy. Competence to make authoritative evaluations of drugs, chemicals and toxic agents with regard to their effects on animals.
- Broad scientific knowledge that include biology, information technology, physics, chemistry/ biochemistry, pharmacology, and toxicology.
- Knowledge to address critical and novel problems, and extends and modifies approaches, precedents, and methods to solve a variety of issues related to drug safety.
- Expert knowledge of broad operating programs to advise senior colleagues and agency officials, and manages significant projects that represent an important segment of the agency's operating programs.
- Ability to communicate verbal and written communication skills and the ability to evaluate and integrate data from multiple sources.

Conditions of Employment:

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

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.

How to Apply: Please submit resume or curriculum vitae with cover letter to**: ond-employment@fda.hhs.gov**. For questions please contact OND External Recruitment Team at **ond-employment@fda.hhs.gov**. Please **reference source code: 20-064BT** in the subject line.

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