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)

Position: Interdisciplinary Scientist

Pay Plan-Series: 401/405/415

Location(s): Silver Spring, MD

Travel Requirements: None

Application Period: 6/16/20 – 7/16/20

Salary: Starting at $102,663 (Cures B and 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 compensated 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 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 manufacturers in support of New Drug (NDA) and Investigational New Drug applications (INDAs) , and to determine if candidate drugs are safe and effective.

Position Summary:

The Interdisciplinary Scientist reviews and evaluates drug applications and communicates conclusions with a multidisciplinary review team. Reviews nonclinical data and communicates safety findings, evaluates nonclinical sections of product labeling, makes regulatory recommendations and meets with industry representatives recommendations. Serves as a CDER resource for nonclinical safety assessments participating in work groups or subcommittees.

Supervisory responsibilities: None

Duties/Responsibilities:

The functions of this position can be performed within any of the pharmacology/toxicology or clinical drug review divisions located within the Office of New Drugs. The nature of the work can be performed by persons with education and experience in molecular, cellular or systems biology, pharmacology and toxicology.

The Interdisciplinary Scientist (hereafter Reviewer) reviews in silico, in vitro, ex-vivo and animal data submitted to IND Applications , NDAs, and Biological License Applications (BLAs) to evaluate:

- the 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.

Use nonclinical data to recommend a first-in-human (FIH) dose range that is safe within the clinical trial context and therapeutic in patients. Employs advanced scientific knowledge for human dose selection 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.

Communicate conclusions on the FIH dose range and the clinical limit dose to the multidisciplinary review team and proposes clinical safety monitoring based on nonclinical data.

Review nonclinical data throughout the drug development process and communicate any new safety findings to the FDA review team, in a formal or informal format. Evaluate specialized

nonclinical studies such as animal efficacy studies via the Animal Rule for medical countermeasures.

Provide comprehensive summary and integrated evaluation of the nonclinical data submitted in INDs (and amendments), NDAs, and BLAs (and supplements) are prepared for supervisory concurrence. 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 are integrated with the conclusions of other team members.

Evaluate whether nonclinical 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. Collaborate with other Divisions or Offices and Centers, as appropriate.

Meet with industry representatives to discuss nonclinical 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.

Make regulatory recommendations, such as clinical hold (INDs) and drug approval (NDAs/BLAs) decisions, based on nonclinical data. In making regulatory decisions and providing internal and external recommendations, the Reviewer follows FDA and ICH guidance documents and internal practices and policies, and thus has knowledge of disease-specific, nonclinical, and multi-disciplinary guidance documents. Make determinations as to whether the nonclinical studies support continued drug development in the patient population being studied.

Attend 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.

Attend courses related to the development of medicinal products. Apply scientific and regulatory 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.

Serve as a CDER resource for nonclinical safety assessment by participating in specialized working groups or subcommittees.

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

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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 more 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.

Click here to learn more about disability employment and reasonable accommodations or how to contact an agency.

Professional Experience/Desirable Qualifications:

- Knowledge and experience in in molecular, cellular or systems biology, pharmacology and toxicology.
- Experience in scientific methods and techniques related to the non-clinical data, pertinent laws, regulations, and Agency policy.
- Demonstrated experience in evaluating and integrating data from multiple sources.
- Mastery knowledge of scientific methods and techniques related to the nonclinical data, pertinent laws, regulations, and Agency policy.

Key requirements will include:

Employs advanced scientific knowledge for human dose selection 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. The Reviewer will communicate conclusions on the FIH dose range and the clinical limit dose to the multidisciplinary review team and proposes clinical safety monitoring based on nonclinical data.

Desirable Education:

Candidates with doctorate degree and specialized experience in neuroscience, immunology, pathology, cancer/molecular biology, or ophthalmology from an accredited university are highly encouraged to apply.

Competitive candidates will have earned a doctoral degree in one of the following:

General Natural Resources Management and Biological Sciences Series, 0401

Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position. **Or** Combination of education and experience: Courses equivalent to a major plus appropriate experience or additional education.

Pharmacology Series, 0405

Degree: major in an appropriate biological, medical, veterinary, or physical science, or in pharmacy that included at least 30 semester hours in chemistry and physiology and 12 semester hours in pharmacology.

Toxicology Series, 0415

Degree: toxicology; or an appropriate discipline of the biological, medical, or veterinary sciences that included at least 30 semester hours in chemistry, biochemistry, or physiology, and 12 semester hours in toxicology.

The degree must be from an educational program from an accrediting body recognized by the

U.S. Department of Education at the time the degree was obtained. Foreign graduates must have their transcripts and degrees evaluated by a credential evaluation service that is recognized by the National Association of Credential Evaluation Services (NACES) or the Association of International Credentials Evaluators (AICE). Candidates must be U.S. citizens. Permanent U.S. residents may apply for staff fellowship appointments.

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: CDER-ONDPharmTox.Employment@fda.hhs.gov. For questions please contact the OND External Recruitment Team at ond-employment@fda.hhs.gov or 301-796-0800. Please **reference source code: 20-065BT** in the subject line.

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