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 Regulatory Policy (ORP)

Position: Supervisory Regulatory Counsel

Pay Plan-Series: AD-301-Level D

Location(s): Silver Spring, Maryland

Travel Requirements: No travel requirements

Application Period: August 24, 2020 to September 21, 2020

Salary: Starting at $121,316 (CURES Band D_)

Area of Consideration: United States Citizens or Nationals

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 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 and prescription drugs, including biological therapeutics and generic drugs. The Office of Regulatory Policy (ORP) provides Center oversight and leadership in the development of regulations, policies,

procedures and guidance's that affect the drug approval process, and in the development of new legislation.

ORP also provides Center oversight and leadership in the disclosure of official records and information under the Freedom of Information Act, Privacy Act, other statutes, and Food and Drug Administration's public disclosure regulations.

The Supervisory Regulatory Counsel manages the CDER program responsible for (1) CDER's compliance with the Paperwork Reduction Act of 1995 (PRA) and, secondarily, (2) the FDA's patent term extension requests received from the U.S. Patent and Trademark Office (PTO). The Supervisory Regulatory Counsel provides leadership and supervision to the staff tasked with properly applying the requirements of the PRA to CDER's work. As part of his/her PRA duties, the Supervisory Regulatory Counsel serves as the Assistant Reports Clearance Officer (ARCO) for CDER which includes, among other duties, managing CDER's information collection review (ICR) inventory and consulting with the FDA PRA staff in identifying information collections that need to be undertaken or extended. The Supervisory Regulatory Counsel also oversees the staff's work in responding to requests from medical product sponsors for patent term extensions. These requests are made to PTO but their resolution is dependent on receiving drug development information from FDA Centers, including the Center for Drug Evaluation and Research (CDER), Center for Biologic and Evaluation Research (CBER), Center for Device and Radiological Health, and Center for Veterinary Medicine.

Position Summary:

As a principal advisor to the Director and Deputy Director, Office of Regulatory Policy (ORP), on PRA and patent term extension matters, the Supervisory Regulatory Counsel is responsible for planning, coordinating, and evaluating these programs and activities. The Supervisory Regulatory Counsel assumes the primary responsibility for ensuring that documents developed in the assigned areas are consistent with statutory requirements and existing policy, that their need is justified, and that adequate reviews have been completed. The Supervisory Regulatory Counsel applies administrative and program management principles and knowledge to efficiently manage the program. Staff performance outcomes are monitored, tracked and resources are allocated and adjusted, as necessary, to meet office needs and performance goals. Proactively communicate changes, progress, and barriers to progress to the Deputy Office Director.

Supervisory responsibilities:

The Supervisory Regulatory Counsel heads a staff of regulatory and project management professionals, advising the staff in the field of regulatory and pharmaceutical compliance. The Supervisory Regulatory Counsel is responsible for reviewing a range of related issues within the Office, across the Center and from other medical product Centers, and for participating in a range of functions related to the PRA and implementing patent term restoration provisions. The

staff, under the direction of the Supervisory Regulatory Counsel, has knowledge of the Food, Drug, and Cosmetic Act, the Public Health Service Act, the Paperwork Reduction Act (PRA), and the patent term restoration provisions of the Drug Price Competition and Patent Term Restoration Act, the Generic Animal Drug and Patent Term Restoration Act, and the Leahy-Smith America Invents Act that requires FDA to provide important information to PTO so that an applicant's patent term extension request can be properly determined.

Duties/Responsibilities:

The PRA was enacted to control the amount of information that the federal government collects from the public, including regulated industries, to ensure that federal agencies do not overburden the public with federally sponsored data collections. It ensures that the information federal agencies collect serves a useful purpose. Compliance with the PRA is essential because legal collection of vital information to fulfill the Agency's mission can only be accomplished with approval from the Office of Management and Budget's (OMB). Examples of FDA-sponsored information collections include the data submissions required to support drug development, drug approval process and related post market submissions, registration and listing of companies manufacturing or distributing FDA regulated products, and certain drug labeling.

The patent term restoration provisions of the Drug Price Competition and Patent Term Restoration Act, the Generic Animal Drug and Patent Term Restoration Act, and the Leahy-Smith America Invents Act require that FDA provide important information to PTO so that an applicant's patent term extension request can be properly determined. It is important that the patent life of a medical product (such as a drug, device, or biological product) receive the appropriate patent life in order to reward the innovation demonstrated by the patent holder but not extend a patent longer than set forth by law so that innovation and competition are properly balanced. The important information that FDA, through the work of this staff, provides to the PTO includes the length of time that elapsed in the FDA review process and whether the applicant is indeed eligible for such a patent term extension.

The Supervisory Regulatory Counsel directs the staff and their work. He/she (1) counsels and trains members of the staff, (2) explains critical and significant legal, regulatory, and compliance concepts; (3) establishes methodologies, procedures, guidance, and policies, (4) assigns incoming documents; (5) reviews draft documents and responses and provides first level signoff for outgoing documents; and (6) sets and communicates priorities and performance goals. The Supervisory Regulatory Counsel handles complex and difficult assignments of national scope and significance regarding the PRA and patent term extensions. He/she participates in and leads regulatory projects, directs and supports implementation of relevant new laws and regulations; and provides technical and non-technical guidance to CDER and FDA senior level officials and stakeholders. Interactions with FDA, HHS, OMB, and PTO officials are effective in developing paperwork reduction and patent term extension policies and resolving issues.

EEO Responsibility:

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.

The incumbent, in conjunction with his/her supervisor, develops an affirmative employment plan for the area supervised including appropriate objectives and goals; and monitors and periodically assesses progress. Keeps informed of, supports, and communicates to employees EEO policies, plans and programs. Seeks out and utilizes available resources, including appropriate personnel generalists/specialists, EEO specialists, and training resources in conducting these responsibilities. Incumbent will be appraised on the effectiveness of his/her performance. Click here to find out additional information about the Equal Employment Opportunity (EEO) for federal employees & job applicants.

Professional Experience/Desirable Qualifications:

- Ability and demonstrated experience in leadership principles and concepts.
- Demonstrated skills in process organization and workload management.
- Demonstrated ability to identify and analyze problems; weigh the relevance and accuracy of information; generate and evaluate alternative solutions; and make recommendations.
- Ability to communicate orally and in writing and work with staff at all levels of the organization and varying levels of domain expertise; demonstrated ability to collaborate across boundaries to build strategic relationships and achieve common goals.
- Ability to work independently and as a contributing collaborative team member.
- Ability to organize time effectively, determine priorities, and move work forward.

Key requirements will include:

Knowledge of regulatory practice, policies, and procedures. Priority will be placed on candidates with relevant experience in working with the Paper Reduction Act.

Desirable Education:

A juris doctorate degree from an accredited institution of higher learning.

Conditions of Employment:

Security Clearance:

This position requires a Non- Sensitive/Moderate Risk security clearance.

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) 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: Submit resume or curriculum vitae with cover letter by September 21, 2020 to: CDER-ORP-Cures-Hiring@fda.hhs.gov. **Please reference Job Code: 20-ORP-37 Supervisory Regulatory Counsel in the subject line.** For questions please contact Amanda.Wyatt@fda.hhs.gov

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