TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Policy (OP)

Position: Regulatory Counsel

Location(s): Silver Spring, Maryland

Travel Requirements: This position requires up to 25% travel.

Application Period: Monday June 8, 2020 through Tuesday July 7, 2020

Salary: Salary is commensurate with education and experience.

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 are safe and effective.

The mission of CDRH is to protect and promote the public health by performing essential public health tasks to ensure that medical devices and radiological health products are safe and effective for people in the United States. The Office of Policy helps lead all policy-related activities at CDRH by: providing oversight and direction in the development and review of, among other items, regulations, orders, guidance, and policy concerning medical devices and radiation-emitting products; coordinating and collaborating with offices within CDRH and FDA to facilitate the development and review of such documents, providing leadership and expertise in CDRH legislative activities, including the development and analysis of legislation, responses to congressional inquiries, and briefings for congressional members and their staff; providing solutions to complicated issues CDRH faces; providing review and analysis of CDRH work product to ensure compliance with the Federal Food, Drug and Cosmetic Act, the Paperwork Reduction Act and other statutory provisions as well as relevant regulations .

Position Summary:

The selected candidate will be primarily responsible for analyzing, reviewing, drafting, editing, and developing regulations, orders, notice, guidance, and other policy documents;; preparing, developing, analyzing, reviewing, and drafting responses to citizen petitions, petitions for stay of action, and/or petitions for reconsideration; drafting legislative proposals and analyzing legislation; and providing advice on the impact of recently enacted legislation, interpreting, analyzing, and providing advice on laws, regulations, and policies applicable to the Food and Drug Administration, specifically for medical devices and radiological health products; and providing administrative support regarding the policies and procedures relevant to the issuance of and writing regulatory documents.

Duties/Responsibilities:
This position is in the Food and Drug Administration (FDA), Center for Devices and Radiological Heath (CDRH), Office of Policy, in Silver Spring, Maryland. As a Regulatory Counsel in OP, the candidate will:

- Provide advice on the impact of recently enacted legislation, interpreting, analyzing, and providing advice on laws relevant to medical devices and radiological health products;
- Make major recommendations and decisions related to policy formulation in connection with changes and significant developments in the field/industry, and prospective changes in programs and policies as the result of new legislation,;
- Develop regulations, policies, and programs involving complex and high priority matters affecting the regulation of medical devices and radiological health products;
- Draft and critically review documents related to policy and program proposals, including regulations, citizen petition responses, guidance, proposed legislation, and policy documents;
- Write and establish policies and procedures that ensure the sufficiency and procedural adequacy of policy documents and policy initiatives.
- Interpret and apply existing policies, setting precedents that affect internal and industry program activities and the marketing of regulated products in which CDRH has jurisdiction.
- Serve as an organizational expert in analyzing the impact of existing or proposed legislation on FDA regulations, and policies.
- Use technical expertise to develop complex regulations, guidance and/or policies that impact multiple FDA components.

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.

Professional Experience/Key Requirements:

To qualify for this position, you must possess technical experience including:

- Knowledge of the various titles of law applicable to the Agency's mission in the regulation and oversight of medical device and radiological health products.
- Knowledge of other pertinent regulatory information in agency manuals, reference systems, directives, issuances, precedent decisions, court decisions, and commercial publications.
- Ability to draft a variety of complex documents, reports, memoranda, briefs, press releases related to regulatory requirements, opinions and responses to citizen petitions, petitions for stay of action, and/or petitions for reconsiderations for a variety of audiences.
- Skill in the analysis, evaluation, and interpretation of complex Federal statutes and regulations and related background.
- Ability to present findings and recommendations in policy terms, both verbally and in writing.
- Ability to identify and clearly articulate problems, present proposals and provide expert authoritative advice and guidance on the regulatory program segment(s), functions, and activities of the Center that includes providing regulatory advice and guidance to Center program managers.
- Ability to meet and deal effectively on behalf of the Center.

Desirable Education:
It is strongly desired that candidates possess a professional degree (M.S., J.D. or Ph.D.) or a related degree and experience in the regulation of devices.

Conditions of Employment:

- One-year probationary period may be required.
- Background and/or Security investigation required.
- U.S. citizenship is required.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- 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. 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 electronic resume or curriculum vitae, cover letter containing a brief summary of scientific accomplishments, and copy of transcripts to CDRHRecruitment@fda.hhs.gov with Job Reference code ***"CDRH-OP -2020-LKI-01"*** in the subject line. Applications and all supporting documentation will be accepted through **July 7, 2020**.

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

FDA is an equal opportunity employer.