Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Food Safety & Nutrition (CFSAN)
Office of Regulations and Policy (ORP)
Regulatory Counsel

Application Period: September 22, 2023 - October 13, 2023

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Regulatory Counsel

Series: 0301 (Miscellaneous Administraton and Program Series)

Location(s): Remote

Salary: Starting at $132,368

Work Schedule: Full Time

Full Performance Band Level: Band D

Cures Band(s): Band D

Travel Requirements: Up to 25%

Bargaining Unit: 3591, National Treasury Employee Union

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

This position is being filled under a stream-lined 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 this authority. Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

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.

CFSAN is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

Duties/Responsibilities

This position is in the Regulations Development Staff (RDS) in the Office of Regulations and Policy (ORP), Center for Food Safety and Applied Nutrition (CFSAN or the Center), Food and Drug Administration (FDA), Department of Health and Human Services (DHHS). RDS advises Center and FDA Foods Program staff on the administrative procedures for rulemaking, guidance documents, other policy documents, legislative matters (such as technical assistance on bills and drafting legislation), and delegations of authority. RDS leads the Center's evaluation of existing regulations to determine whether they are accomplishing their intended purpose or need revision or revocation. RDS also drafts, reviews, and edits proposed and final regulations and other Center documents to be published in the Federal Register. RDS provides Center-level leadership and coordination regarding briefings with other parts of the FDA or Federal government regarding CFSAN regulations, guidance documents, and other legislative and policy matters, often in coordination with CFSAN's Office of Executive Programs.

The incumbent serves as a Regulatory Counsel in the Regulations Development Staff, Office of Regulations and Policy and is responsible for planning, scheduling, and implementing the development, analysis, and evaluation of priority regulatory and public health policy initiatives, documents, and projects.

- Develops, evaluates, and reviews regulatory products, such as regulations, guidance documents, notices, and citizen petition responses, involving sensitive, complex, and high-priority matters relating to human foods, including food safety, nutrition, and labeling.
- Constructs regulatory judgments about whether regulations and policies developed in the assigned areas are consistent with statutory and regulatory requirements and existing policy, whether their need is justified, whether adequate science, analysis, and support exists, and whether critical, regulatory, policy, and scientific issues have been resolved.
- Directs the Center's evaluation of existing regulations to determine whether they are efficiently and effectively accomplishing their intended purpose or need to be revised or revoked.
- Directs or substantially participates in working groups of scientific, regulatory, policy, economic, and legal experts within CFSAN and across FDA to identify and define major regulatory issues that have broad impact and consequences and the national and international level.
- Coordinates and translates critical input from such experts to develop and review policy and regulatory recommendations and documents (e.g., regulations, guidance documents) for senior CFSAN and FDA leadership. Collaborates with senior level officials to arrive at scientifically and legally supportable, risk-based regulatory decisions.
- With limited supervision, initiates, coordinates, monitors, and reviews the development and implementation of a diverse portfolio of policies, national and international

standards, procedures (including rulemaking initiatives, guidance for industry and FDA staff, international food safety equivalency determinations, and/or internal Center/ Agency procedures) to address critical food safety or nutrition priorities with national and international impacts.
- Participates in intra/inter-Agency task forces or regulatory working groups that perform analytical studies and other analyses that lead to the development of recommendations relating to key government functions and the future direction of FDA programs.
- Leads implementation of recommendations and proposals that may implicate substantial FDA resources and policies. Represents FDA/Center/Office at internal and external meetings, including with members of Congress, industry, consumer and public health interest groups, and academia, on issues of national or international significance.
- Responds to and manages the Center's response to DHHS, interagency (e.g., DOJ, USDA, EPA, USTR), and Office of Management and Budget comments on draft regulations, guidance, and other policy documents.
- Advises on legal briefs prepared in response to litigation involving the Center's regulatory documents (e.g., regulations, guidance, citizen petition responses, enforcement actions).
- Identifies, articulates, addresses, and resolves unique, far-reaching, and previously unresolved and precedent-setting problems and complex issues relating to critical foods, dietary supplements, and cosmetics.
- Provides regulatory and policy advice to the RDS Supervisory Regulatory Counsel, CFSAN leadership, the FDA Commissioner and other high-level FDA and DHHS officials on policy status, plans, trends, and significant problems related to the regulation of critical food products within CFSAN's purview.
- May be assigned similar work in other regulated product areas based on the business needs of the Center.

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959 must be registered with the Selective Service.
- One year probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.

- More than one selection may be made from this job announcement.
- Background Investigation/Security Clearance is required. All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
    a. ***Qualified*** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
    b. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following required qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

Desired Professional Experience:

- A juris doctorate degree from an accredited institution of higher learning.
- Expertise in the development, monitoring, coordination, and implementation of FDA policies and regulatory related issues to foods, dietary supplements, and cosmetics; responds to inquiries and correspondence directed to the Center Director, Commissioner, Principal Deputy Commissioner, and other senior FDA staff.
- Experience using laws to develop and review regulatory or policy documents concerning complex and high priority matters affecting the regulation of foods, including dietary supplements.
- Expertise in applying regulatory and policy issues and expert regulatory drafting and review experience to lead major initiatives, such as the development of proposed and final rules, draft and final guidance documents, and other policy documents related to FDA's regulation of foods, dietary supplements, and cosmetics.
- Experience in reviewing documents drafted by other staff, to include drafting and critically reviewing team responses to complicated topics that raise various regulatory and policy issues and affect the regulated industry.
- Experience analyzing, interpreting, and implementing complex legislative matters relating to authorizing statutes.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university.For more information about this requirement, please visit the U.S. Department of Education website for Foreign Education Evaluation.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Background Investigation/Security Clearance Requirements: A background investigation is required. All employees must pass a security background investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.

Ethics Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information please visit the FDA Ethics web page: https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity

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

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.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

How to Apply

Submit resume or curriculum vitae with cover letter by the closing date as identified above to CFSAN-Cures@fda.hhs.gov. Candidate resumes may be shared with hiring official within the CFSAN with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". For questions please contact CFSAN-CURES@fda.hhs.gov. Please reference Job Reference ID: ***"ORP Regulatory Counsel"*** when applying.

Announcement Contact

For questions regarding this Cures position, please contact CFSAN-CURES@fda.hhs.gov. Please reference Job Reference ID: ***"ORP Regulatory Counsel"***

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

FDA is an equal opportunity employer.