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)

Application Period: October 26, 2023 – November 15, 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: Deputy Director, Supervisory Regulatory Counsel

Series: 0301 (Misc. Administraton and Program Series)

Location(s): Remote

Salary: Starting at $177,123

Work Schedule: Full Time

Full Performance Band Level: Band F

Cures Band(s): Band F

Travel Requirements: Up to 25%

Bargaining Unit: 8888, Nonbargaining Unit

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.

This position is located in the Office of Regulatory and Policy (ORP), within the Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (FDA), U.S. Department of Health and Human Services (HHS). The incumbent serves as the Supervisory Regulatory Policy Advisor and Deputy Director to the Director of the ORP. Participates with the Director in the development of CFSAN regulations and guidance documents, and reviews and clears draft regulations, guidance documents, and Federal Register notices developed by CFSAN, other components of the Food and Drug Administration (FDA), or by other agencies.

Duties/Responsibilities

The Deputy Director serves as an alter ego to Director, ORP, and fully shares with the Director the direction of most phases of the ORP's programs. Also, the incumbent, along with the Director, ORP, provides leadership, program direction and general oversight for policy issues involving Center-regulated food or cosmetic products in collaboration with the Center Director, and other members of the FDA senior management team. The incumbent will perform the following duties:

- Serves as a major FDA focal point providing technical, legislative, and policy expertise on important food policy issues that require coordination and negotiation between senior officials and staff in FDA and the Department of Health and Human Services.
- Provides regulatory leadership, advice, and analysis for development and implementation of policy and initiatives.
- Serves as the senior regulatory, policy, and strategy expert for the ORP and is responsible for developing and implementing strategy and policy for the ORP on behalf of the subject matters experts (food safety medical and scientific experts/advisors) recommendations.
- Acts as an advisor and CFSAN lead for developing, monitoring coordination, and implementation of Foods Program policies. Identifies and assesses emerging complex issues, and advises senior FDA officials, including the CFSAN Center Director, Deputies, and CFSAN Office Directors, of potential and emerging problems areas and the need to formulate appropriate program responses.
- Serves as an authoritative source and expert advisor for developing, monitoring, coordinating, and implementing FDA Foods Program policies related to food safety, labeling, and nutrition.
- Represents FDA as the authoritative Foods Program policy expert in meetings with key stakeholders, including industry, public health and consumer groups, and members of Congress.
- Provides authoritative policy for actions through policy-oriented research and evaluation, including identifying and researching the impacts of FDA Foods Program policies, and proposed alternatives, on FDA programs and national public health and safety.

- Reviews and conducts in-depth analysis of policies and strategies and identifies issues of contemporary and future impact on the ORP and CFSAN and conducts analysis of their implications and alternatives. Provides critical feedback and recommendations to the Director, ORP, regarding policy positions on numerous national level strategic directives and policy statements.
- Prepares and leads briefings to senior FDA officials, and other Federal Senior officials, to enable the Foods Program to fully understand salient points of complicated or complex foods-related issues, regulations, guidance documents, legislation, or policies.
- Serves as an authoritative source, expert advisor, and Foods Program lead for the development, monitoring, coordinating, and implementation of Agency regulations and policies related to food safety, food labeling and nutrition, dietary supplements, infant formula, food ingredients and food contact substances, color certifications, cosmetics, food inspections, other food-related issues.
- Authoritatively and independently researches, reviews, evaluates, and formulates a wide variety of written materials on complex policies, regulations, legislation, and laws related to food safety, food labeling and nutrition, dietary supplements, infant formula, food ingredients and food contact substances, color certifications, cosmetics, food inspections, other food-related issues.
- Provides authoritative policy inputs for regulatory actions through policy-oriented research and data evaluation and expert knowledge of the Administrative Procedure Act and FDA's authorizing statutes, including the Federal Food, Drug, and Cosmetic Act, and implementing regulations and guidance documents.
- Prepares and leads briefings to senior officials, including Center Director and Deputies, FDA Commissioner and Associate Commissioners, and other Federal Senior officials, to enable the Foods Program leadership and other senior staff to fully understand salient points of complicated or complex foods-related issues, guidelines, legislation, or policies.
- Represents, negotiates, promotes, and defends the policies and positions of the Foods Program before other FDA organizations, Federal agencies, State and local governments, tribes, industry, academia, consumer organizations, Congress, and national and international organizations, and the scientific community.

Supervisory Responsibilities:

Supervisor provides occupational specific technical and administrative direction 25 percent or more of the time to three or more subordinate employees performing the work and functions of the organization. * Obtains resources and identifies strategic objectives for the organization. * Defines jobs, selects employees, and assigns work; defines technical work requirements and milestones; evaluates the organization and employee accomplishments by accepting or rejecting work products; and presents and defends organization and employees work to senior management and other offices. * Recommends employee promotions and recognition;

approves leave; implements performance modifications and takes corrective actions as appropriate. * Provides equal opportunity in all Federal human capital and employment programs regardless of race, color, gender, national origin, religion, age, disability, genetic information, sexual orientation, affiliation or non-affiliation with a labor organization, political affiliation, status as a parent or gender identity. * Provides employees resources and information that insures a safe and healthy work environment.

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 supervisory 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.*

Title 21 Minimal Qualifications:
Education: A law degree, specifically a LL.M. or J.D. The degree must be from an accredited program or institution.
OR
Experience: Comparable regulatory experience focused on interpreting laws, rules, regulations, or policies; or develop or analyze regulations and policies forregulated products.

Position Desired Skills, Experience, or Education:

- A juris doctorate degree from an accredited institution of higher learning.
- Experience in communicating and negotiating with diverse scientific, legal, and management professionals on a wide range of issues, such as those related to foods, dietary supplements, and cosmetics.
- Experience providing advice and guidance on the regulatory program segments, functions, and activities that include providing regulatory advice to clients or federal program managers.
- Experience in analyzing, evaluating, and interpreting complex materials, such as Federal statutes, regulations, Executive Orders, State regulations, and cases; ability to draft highly complex documents related to regulatory requirements and Center priorities.
- Experience in presenting complex materials, both orally and in writing, in an understandable manner, appropriate to the target audience.
- Expert skill in reviewing draft versions, prepared by Regulatory Counsels or other Agency staff, of highly complex regulatory documents related to regulatory requirements and Center priorities to ensure that the documents are legally sound and appropriate.
- Demonstrated leadership abilities and solid judgment.

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.

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, cover letter, and copy of all college transcripts and/or foreign education evaluation (if applicable) by the closing date as identified above to CFSAN-CURES@fda.hhs.govand include the job reference ID: ORP Deputy Director. 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 and include the job reference ID: ORP Deputy Director.

Announcement Contact

For questions regarding this Cures position, please contact CFSAN-CURES@fda.hhs.gov.

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

FDA is an equal opportunity employer.