Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Human Foods Program (HFP)
Human Foods Program (HFP)/Office of Policy and International Engagement (OPIE)
Supervisory Science/Regulatory Policy Analyst/Regulatory Counsel
Super Office Director

Application Period: August 1, 2024 – August 30, 2024

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: Super Office Director (Supervisory Science/Regulatory Policy Analyst/Regulatory Counsel)

Series:

0301, Science/Regulatory Policy Analyst
0301, Regulatory Counsel

Title 21 Band(s):

0301, Science/Regulatory Policy Analyst Pay Table 4, Band G
0301, Regulatory Counsel, Pay Table 5, Band G

Full Performance Band Level: Band G

Location(s): College Park, MD

Work Schedule: Full Time

Salary: Starting at $213,491

Travel Requirements: Up to 25%

Bargaining Unit: 8888, Non-bargaining 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 is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective; that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe; and that all such products marketed in the U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Human Foods Program (HFP) is to protect and promote the health and wellness of all people through science-based approaches to prevent foodborne illness, reduce diet-related chronic disease, and ensure chemicals in food are safe.

Duties/Responsibilities

The Office of Policy and International Engagement (OPIE) is responsible for providing oversight and leadership in the development of all regulations, guidance, policies, procedures, citizen petition responses, and new legislation impacting HFP. In addition, the Super Office leads cross-cutting HFP policy development, special projects, and oversees international food safety and nutrition policy and programs and/or trade issues. The OPIE leads efforts to proactively engage in strategic partnerships globally for the safety of food imports/exports and food safety systems. The Super Office Director oversees a range of regulatory and policy issues that affect numerous fields connected to Human Food activities. These program responsibilities cover diverse and distinct subject areas including dietary supplements, nutrition, and chemical and microbiological food safety both nationally and internationally. In addition, the incumbent performs the following:

- The Super Office Director serves as a senior advisor to, and a spokesperson for the Deputy Commissioner for Human Foods, Principal Associate Commissioner, and Associate Commissioner for Human Foods Policy in matters related to the development and implementation of regulatory policies and policy documents (i.e., guidance documents, regulations, Federal Register notices, legislative text, and citizen petition responses) affecting the HFP's broad national and international programs and activities. In this capacity, the incumbent provides expert advice, guidance, and counsel to the Deputy Commissioner for Human Foods, Principal Associate Commissioner and Associate Commissioner for Human Foods Policy during all phases of policy development and implementation, which includes highlighting potential challenges, obstacles, and risks and ensuring that impacts to other offices are considered and appropriately addressed. The incumbent's advice, guidance and counsel is also relied upon to make recommendations for new policy and program initiatives that are needed to accomplish HFP's public health mission to protect and promote public health, assure the safety of the food supply, and advance the Agency's initiatives. These responsibilities are accomplished through executive leadership and oversight of the Office of Regulations, the Office of Policy Initiatives and Projects, and the Office of International Engagement.

- Provides executive leadership for international activities and initiatives, including participation on U.S. trade delegations and in trade negotiations to support resolution of trade concerns related to imports and exports of FDA-regulated products; development and maintenance of systems recognition and equivalence agreements; and coordination of audits, agreements, and other bilateral activities involving food a safety, nutrition, and labeling with foreign governments, embassies, and international stakeholders.
- Provides executive leadership for the development of all documents submitted to the Office of the Federal Register, including regulations and guidance documents, as well as for the development and evaluation of legislative proposals and materials related to implementing, amending, or modifying FDA laws and regulations.
- Oversees healthy equity and environmental policy activities for the HFP, including equity assessments and environmental reviews prepared to ensure compliance with the National Environmental Policy Act, in coordination with other relevant FDA components.
- Oversees regulatory and disclosure policy development and analysis activities on behalf of the HFP and coordinates resolution of policy issues involving FDA-regulated food products. Works closely with the Associate Commissioner for Human Foods Policy on such activities.
- Works with executive leadership to provide direction and monitoring of HFP policy activities executed throughout all HFP Offices, and providing oversight of these activities, where appropriate, in conjunction with the Associate Commissioner for Human Foods Policy In addition to directing work on policy related activities, monitors progress towards organizational goals, makes short- and long- range goal adjustments, and is held accountable for ensuring successful fulfillment of program goals and objectives.
- Leads coordination of development and review of regulatory policy documents and related policy activities with other FDA Centers; the Office of Chief Counsel; the Office of Policy, Legislation, and International Affairs; the Office of the Commissioner; the Department of Health and Human Services (HHS); and the Office of Management and Budget. Participates in and contributes to top level HFP, Agency, and HHS discussions, meetings, and conferences involving regulatory policies and policy documents.
- Represents the Agency and establishes and maintains relationships with top level FDA and HHS Officials, national/international industry representatives, Members of Congress, counterparts from other Federal, State, and local government agencies, foreign government representatives, academia, and consumer and other groups to: secure, exchange and provide information regarding regulatory policies and policy documents; discuss questions, problems and issues involving policy considerations; present authoritative recommendations and conclusions reflecting the Agency's position on matters related to existing and proposed policies, regulations and proposed legislation; and make and deliver decisions and commitments concerning regulatory policies and policy documents. Explains, defends, and negotiates the Agency's position concerning guidance, policy, and regulatory issues associated with food safety and nutrition initiatives.

- Ensures that the organizational structure of the Office provides for uniformity, optimum effectiveness, and operational efficiency. Analyzes and defines significant obstacles that could hinder program accomplishments and recommends changes and initiates action to ensure effective resources utilization and the elimination of duplication. Promotes and encourages intra- and inter-Program cooperation to achieve program objectives.
- Manages the personnel and financial resources of the Office ensuring that resources are allocated and utilized in accordance with the identified priorities and core functions of the HFP.

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. * 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.
- 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.*

Minimum Requirement (for Supervisory Regulatory Counsel)

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 for regulated products.

Desired Professional Experience or Education:

- Multi-year experience managing a complex policy program, especially with experience in critical food safety and nutrition policies and regulations.
- Expertise knowledge regarding the Food, Drug, and Cosmetic Act, including key provisions such as the Food Safety Modernization Act and their accompanying regulations.
- Demonstrated leadership 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 international affairs, including expertise in the development of trade policies and international standards; and negotiations with foreign government officials.
- Demonstrated knowledge of Federal regulatory systems, including interactions up the chain of command and engagement with other federal agencies, state officials, and Congressional oversight.
- Experience communicating sensitive, controversial, and/or highly technical information in a clear way and working with staff at all levels of the organization and varying levels

of domain expertise; excellent listening skills and a commitment to communicate in a timely manner.
- Experience leading and managing subordinate supervisors and teams effectively, with a track record of strategic decision-making and achieving business objectives.
- Demonstrated experience developing networks and building alliances; collaborating across boundaries to build strategic relationships and achieve common goals.
- Experience in identifying internal and external politics that impact the work of the organization, perceiving organizational and political realities, and acting accordingly.

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: Non-Critical Sensitive – High Risk

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. Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary 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.

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

How to Apply: Submit resume or curriculum vitae with cover letter and a copy of all transcripts (with foreign credential evaluation, if applicable) by the closing date as identified above to hfpexecutiveresources@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 hfpexecutiveresources@fda.hhs.gov. Please reference Job Reference ID: OPIE, Super Office Director.

Announcement Contact

For questions regarding this Cures position, please contact hfpexecutiveresources@fda.hhs.gov. Please reference Job Reference ID: OPIE, Super Office Director.

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

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