Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Food Safety and Applied Nutrition (CFSAN)
Office of Compliance (OC)
Senior Advisor for Critical Foods Enforcement and Compliance

Application Period: March 27, 2023 – April 12, 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: Senior Advisor for Critical Foods Enforcement and Compliance

Series: AD-696

Location(s): College Park, MD

Salary: Starting at $155,700

Work Schedule: Full Time

Full Performance Band Level: Band E

Cures Band(s): Band E

Travel Requirements: Up to 25% travel

Bargaining Unit: 8888

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.

The mission of the Center for Food Safety and Applied Nutrition (CFSAN) protects and promotes public health by ensuring that the nation's food supply is safe, sanitary, wholesome, and

honestly labeled, and that cosmetic products and dietary supplements are safe and properly labeled.

The Office of Compliance (OC) serves as the primary contact between the Center and the Food and Drug Administration's (FDA) field organization and Office of Chief Counsel. The OC's primary responsibilities include: Managing of compliance programs, field assignments, and work plans; Initiating and/or coordinating the planning, development, publication and promotion of field guidance documents for the Center for Food Safety and Applied Nutrition (CFSAN)-regulated food and cosmetic products to implement sound public health practices, food safety/security interventions, compliance/enforcement strategies, and regulatory programs; Providing information, training and technical assistance to implement guidance and regulations; Reviewing proposed regulatory actions and recalls for adequacy of evidence and consistency across programs; Overseeing the development of compliance and enforcement strategies for routine and emerging compliance challenges; Monitoring and mining information from internal and external sources to identify trends or emerging compliance and enforcement related issues that may influence the Center's area of regulatory responsibility. Providing data and other information on field accomplishments to support the Center's evaluation of programs and assignments, developing of new assignments, assessing of the industry or any other relevant FDA purpose; and overseeing, monitoring, and evaluating the food facility registration data base.

Duties/Responsibilities

The Consumer Safety Officer serves as the Senior Advisor for Critical Foods Enforcement and Compliance providing in-depth expertise for all pertinent regulatory and scientific matters impacting infant formula and critical foods compliance and enforcement, including the Infant Formula and Medical Foods Compliance Program and related policies and procedures in the Center for Food Safety and Applied Nutrition. As the Senior Advisor for Critical Foods Enforcement and Compliance, the incumbent will perform the following as noted below:

- Provides executive compliance and regulatory leadership to the infant formula program, policy, enforcement and/or strategic initiatives.
- Provides strategic guidance and functional oversight in delivering regulatory and policy-based services for the Infant Formula program across the human foods program.
- Implements consistent procedures and policy in coordination with Agency and industry counterparts and provides problem-solving and timely and decisive analysis and advice to address regulatory and policy issues and questions for the Human Foods Program.
- Serves as the Center representative and spokesperson on all aspects of Critical Foods Enforcement and Compliance with other Agency components such as the Immediate Office of the FDA Commissioner, CFSAN Immediate Office of the Center Director, the Office of Chief Counsel, and the Office of Regulatory Affairs, as well as with external stakeholders, such as the Centers for Disease Control, U.S. Department of Agriculture, infant formula industry, and consumer or public interest groups.
- Coordinates and monitors efficient and timely communication with White House, Congressional, Department and Agency leaders, which is required due to public health

importance of this commodity and population served and the potential for supply chain disruption in this industry.

- Implements legislation related to new infant formula and critical foods related obligations and authorities. Identifies programmatic gaps and assists in the development and negotiates Agency support of new legislative proposals to address gaps.
- Oversees all infant formula related compliance and enforcement actions, including reviewing and making decisions with respect to inspectional observations and sampling results to maximize public health protection and minimize supply disruption. Work includes coordinating and developing of compliance and enforcement strategy to include recalls, regulatory meetings, warning letters, and other administrative or judicial action as warranted.
- Determines and provides oversight for personnel and budget resources utilized to address day-to-day compliance and enforcement priorities and operations.
- Manages high priority Center deliverables related to infant formula program capacity building including the revision of the Infant Formula Compliance Program and associated policies and procedures and establishment and training of a new global Infant Formula Inspection Cadre.
- Serves as Compliance and Enforcement expert liaison for high priority deliverables led by other Offices within the Center, including prevention, nutrition, and supply deliverables. Serves as liaison to advise on compliance and enforcement aspects as Office for Critical Foods is established.
- Oversees the coordination of infant formula instructions and inspection schedules to maximize public health protection, reduce impact on supply chain and optimize the use of field resources.
- Advises the Office Director in matters related to the regulatory review of Infant Formula manufacturers and policy issues related to Infant Formula manufacturing processes, microbial pathogen, nutrition policy and supply chain concerns.
- Applies knowledge of the Federal laws, regulations, policies, and guidelines pertaining to the regulation, enforcement and compliance of infant formula and critical foods.
- Applies scientific and regulatory knowledge to assist in developing regulatory policy and guidance documents related to the infant formula and critical foods and providing technical and policy input to support compliance and enforcement actions relating to infant formula and critical foods.
- Provides assistance in and coordinates oral and written responses to both routine and complex inquiries from a variety of stakeholders, including other offices in FDA, other Federal agencies, stakeholders from industry, and State, local and foreign governments.
- Receives meeting requests from various stakeholders and external parties, including manufacturers, trade groups, and other government agencies.
- Reviews and responds to general correspondence, as well as to handle phone inquiries from the field, regulated industry and their lawyers and consultants.
- Evaluates information for project priorities, plans and organizes the work, and sets timelines and schedules for the timely completion of assigned projects.

- Prepares and presents briefings to higher level management and recommends program enhancements.
- Directs the formation of specialized teams to address specific priorities and provides technical expertise for training development and implementation for Agency Infant Formula and Critical Foods staff.

Supervisory Responsibilities: This is not a supervisory role.

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.
- 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 <u>required</u> is preferable and desired. Candidates who do not meet the "desired" criteria will <u>not</u> be excluded from consideration for this position.

<u>Education Requirement</u>:
Consumer Safety Series, 0696:

A. A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work.

   The 30 semester hours may include up to 8 semester hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming.

or

B. Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in paragraph A above, plus appropriate experience or additional education.

<u>Desired Education</u>: The ideal candidate would have a law, advanced science or engineering degree.

<u>Professional Experience:</u> Experience effectively reviewing, evaluating and advising on complex topics requiring a consideration of scientific and regulatory significant aspects within area of expertise; problem solving and negotiating solutions that are constrained by both food and drug law and scientific limitations.; creating and sustaining effective working relationships with FDA and government and industry stakeholders, experience intersecting and communicating with Senior Government Officials on high profile legal, regulatory or policy matters.

<u>Desired Professional Experience</u>:

- Thorough knowledge of a category of products which is difficult to work with because of the science, and/or technologies involved and because the legal and regulatory concepts necessary to enforce the law are complex and/or unprecedented.
- Thorough knowledge of, as well as the intent of, enabling legislation, policies, implementing regulations and procedures, organizational structures, and interrelationships of inspectional/investigative and compliance organizations and programs with each other.
- Mastery of technical and soft skills necessary to set strategic organizational goals, gain support and monitor progress.

- Experience in overseeing the work of others and while exercising important policy-making and policy determining function.
- Experience preparing, editing and delivering a variety of complex written and verbal communications such as briefing papers, options papers, project plans, responses to Congressional or media inquiries, urgent or sensitive matter situational updates, conference presentations or panel discussions, testimony preparation, etc.

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: 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. Please refer to the Ethics Clearance Requirements section.

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

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

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: Applications will be accepted from all qualified internal and external applicants. Please send a letter of interest addressing your experience in the duties and responsibilities of the position, SF-50 for current federal employees only, copy of unofficial transcripts (with foreign credentials evaluation, if applicable) to CFSANExecutiveRecruitment@fda.hhs.gov by **April 12, 2023**. For questions please CFSANExecuetiveRecruitment@fda.hhs.gov. Please reference Job Reference ID: “OC Consumer Safety Officer”

Announcement Contact

For questions regarding this Cures position, please contact CFSANExecutiveRecruitment@fda.hhs.gov

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FDA is an equal opportunity employer.