



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)
Division Director, Division of Enforcement (DE)

Application Period: February 14, 2024 – February 28, 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: Division Director, DE
(Regulatory Specialist)

Series:
0696, (Regulatory Specialist)

Location(s): Remote

Salary: Starting at \$181,551

Work Schedule: Full Time

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: up to 25%

Bargaining Unit: 8888, Nonbargaining

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) 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

The incumbent serves as a Division Director for the Division of Enforcement (DE), Office of Compliance (OC), within the Center for Food Safety and Applied Nutrition (CFSAN), and acts as an authoritative source of information on broad regulatory and enforcement challenges, recommends enforcement strategies, identifies risks and impacts affecting major industry practices and is responsible for the following duties:

- Formulating and implementing organizational strategies, policies, and planning for regulatory and enforcement programs of national scope and impact.
- Providing leadership, program direction, and oversight of program operations with respect to regulatory and enforcement for major agency programs of national scope and impact.
- Coordinating the work across broad groups of stakeholders especially when there are major regulatory issues debated on a national level in the work area, or a requirement to resolve complex, controversial, or unusual matters of major consequence or importance to the agency.
- Providing decision-making authority for the full range of personnel actions and organization design improvements recommended by supervisors of subordinate organizations, including the approval of long-range work plans, and the management of major changes throughout the organization directed, such as major changes to the structure, priorities, and content of the program directed.
- Setting precedents in interpreting and applying existing regulatory and enforcement policy that affected internal and industry program activities and the marketing of regulated products.
- Serves as technical authority on the resolution of the most challenging problems critical to an agency that involved policy decisions or required difficult and extensive interpretation of applicable legislation.
- Preparing authoritative summaries and updates of the regulatory and enforcement issues for leadership awareness and decision-making. Serves as an expert and consultant in the development of new compliance and enforcement strategies or the adaptation of existing strategies for new applications.
- Coordinating cross-cutting issues vital to the Center's compliance and enforcement goals while collaborating with other FDA, State and other partners.
- Performing other duties as assigned.

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. The incumbent leads all

aspects of managing functions within the Division, through branch and team leaders, providing expertise at the Division level. Supervises subordinate supervisors and employees responsible for performing the varied and broad regulatory and enforcement functions of the division related to the highly complex requirements of the Agency which are constantly changing and often involve extensive coordination. 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. Manages and mentors subordinate first line supervisors and employees in the Office of Compliance, Division of Enforcement and embraces opportunities to support diversity, equity, and inclusion efforts. Evaluates budget estimates and justifications and makes appropriate recommendations to the Office Director. Determines the best approach and solution for resolving budget problems and plans for long range staffing needs. Performs administrative and human resources management functions relative to the staff. Tracks recruitment and renewals and oversees interviews and selection recommendations. Identifies new ways to manage constrained resources, e.g., changes in procedures or standards to conserve resources without affecting the quality of output, recommends organizational design changes. Directs, oversees, and coordinates the work of subordinates and team leaders. Provides direct supervision to employees with various levels of skill and experience in achieving program goals, including planning, managing, and directing their work. Assures reasonable equity of performance standards and rating techniques developed by subordinates. Identifies employee competency gaps. Makes selections for subordinate supervisory positions and approves subordinate non-supervisory selections. Reviews and approves or disapproves leave requests. Hears and resolves grievances and serious employee complaints. Reviews and approves serious disciplinary actions. Recommends awards and bonuses for employees and changes in position classification subject to higher level approval. 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.
- 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.*

Education Requirement:

Education: A bachelor’s degree or higher in quality assurance/management, data science, statistics, computer forensics, epidemiology, pharmacy, public health, engineering, food science, law or regulations, or related healthcare or science field. The degree must be from an accredited program or institution.

OR

Experience: Comparable regulatory experience or FDA-regulated product lifecycle experience focused on enforcing and/or ensuring compliance with FDA laws and regulations or experience in one or more of the following:

- Knowledge of the FD&C Act combined with experience in either Current Good Manufacturing Practices (cGMP), or auditing products that the FDA regulates.
- Interpreting the statute, regulations, guidance, and other quality policies to assess compliance, quality, manufacturing performance, or quality management maturity.

- Product development, process development, scale-up, or commercial manufacturing.
- Sterility assurance and microbiological controls.

Professional Experience: Demonstrated experience leading an organization, developing strategies, and communicating on all aspects of regulatory and enforcement compliance.

Desired Professional Experience:

Our ideal candidate will possess:

- Experience with regulatory or enforcement strategy development, and application of regulatory tools to specific cases or fact patterns.
- Experience communicating persuasive technical and legal information to summarize issues and inform decision-making by senior leadership officials, subordinate staff and peers. Excellent listening skills and a commitment to communicate in a timely manner.
- Experience leading group work, working independently and also as a contributing, collaborative team member.
- Demonstrated experience developing networks and building alliances; collaborates across boundaries to build strategic relationships and achieve common compliance and enforcement goals.
- Skill in identifying and analyzing; weighing significance, relevance and accuracy of information; generating and evaluating alternative solutions; making recommendations.

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.

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

How to Apply: Submit resume or curriculum vitae, cover letter, and a copy of all college transcripts (with foreign credential evaluation, if applicable) 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: **OC, Division Director, DE.**

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.

