Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Human and Animal Food Operations (OHAFO)
Office of Human and Animal Food Operations West (HAF-W)
Consumer Safety Officer (National Expert)

Application Period: May 17, 2023 to May 31, 2023

Area of Consideration: Open to current FDA employees only. 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: Consumer Safety Officer (National Expert)

Series: AD-0696

Location(s): Telework Eligible

Salary: Starting at $155,700

Work Schedule: Full Time

Cures Band(s): E, Pay Table 1

Full Performance Band Level: Band E

Travel Requirements: Up to 75% travel

Bargaining Unit: This is a bargaining unit position

This position is being filled under a stream-lined hiring authority, Title 21 of the United States Code (21 US Code 379d-3a) as amended by the 21st Century Cures Act of 2016, section 3072 and the Consolidated Appropriations Act of 2023, Section 3624. 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 the 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 that all such products marketed in the United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured, packaged and regulated. FDA's programs are national in

scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

The Office of Regulatory Affairs (ORA) is at the forefront of building a public health safety net for today's complex, global regulatory environment. ORA professionals work in a range of program areas and locations, with 227 offices and 12 laboratories throughout the United States. As the lead office for all FDA field activities, ORA serves as the agency's direct connection with regulated industry through a) inspections of firms and plants producing FDA-regulated products, b) investigations of consumer complaints, emergencies and criminal activity, c) enforcement of FDA regulations, d) sample collection and analysis, and e) review of imported products.

The mission of the Office of Regulatory Affairs is to protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products. To view our ORA Vision, Mission, and Values please visit: https://www.fda.gov/about-fda/fda-organization/office-regulatory-affairs.

The Office of Human and Animal Food Operations (HAF) oversees the coordination, interpretation and evaluation of the FDA's overall field inspections and compliance efforts in the areas of human and animal food and other products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). Additionally, the HAF program focuses on national and international inspection of a variety of diverse and complex food products and production processes including infant formula, medical foods, low acid canned food and thermal processing, etc.

The HAF Program oversees field operations that encompass both food safety and food defense activities to determine compliance with the Food Safety and Modernization Act (FSMA) as well as other FDA laws and regulations, and to ensure the safety of consumers. In addition, the HAF program routinely coordinates emergency response activities, rapid identification of suspect tainted foods, trace forward, and tracebacks to swiftly address emerging issues which have potential to compromise public health.

As ORA's Expert Investigator, the Consumer Safety Officer (National Expert) (CSO-NE) serves as ORA's subject matter expert on international regulatory affairs and preventive control measures (e.g., PCHF, PCAF, LACF, Seafood HACCP, Infant Formula, Produce) pertaining to human and animal foods.

The CSO-NE, who reports directly to the Deputy Program Director, HAF-W, is expected to have mastery knowledge in these areas of the food industries: Food microbiology, and the preventive controls of regulatory human and animal foods, including hazard analysis and the laws, regulations, and policies of FDA.

Duties/Responsibilities

- Provides technical advice and counsel to CFSAN, CVM, and ORA senior management on identifying the need to draft regulations that affect various food industries, develops new programs and initiatives that affect food industries, and develops agency policies relating to food issues as it relates to the assurance of uniform applications of preventive controls. The incumbent is a recognized authority and spokesperson for issues relative to national / international human and animal food field operations including emergency response activities.
- Incorporates standard modeling and methodology of preventive control measures statistics and risk analysis management, develops broad and complex regulatory programs to ensure preventive control measures are consistent with established laws, policies, and regulations. Drafts or critically reviews documents embodying policy and program proposals and decisions.
- As a liaison, may participate in efforts with national and/or international organizations to establish governmental agreements on international standards for preventive control measures relating to human and animal foods.
- Consults and informs individuals and other Federal agencies regarding the proper application of national and/or international scientific established preventive control measures for human and animal foods to private industries, universities, and foreign governments on the status and safety of human and animal foods.
- Provides authoritative information to individuals, other Federal agencies, private industry, universities, and foreign governments on the U.S. regulatory status and safety of various substances used in human and animal foods.
- Conducts discussions with stakeholders including industry scientists, medical and healthcare professionals, and management officials regarding the development and implementation of regulatory policies and procedures.
- Conducts inspections and investigations relating to the most complex, controversial, and precedent setting scientific and regulatory problems involving human and animal food products, both nationally and internationally. Advises agency leadership about the status of said cases.
- Utilizes strategic problem solving to select projects for intervention and to develop and evaluate the effectiveness of such interventions in reducing the public health risks associated with violative regulated human and animal food products.
- Advises the Program Divisions investigations and compliance organizations in the development and management of the most complex, controversial, and precedent setting regulatory cases involving human and animal food products.
- Serves as a recognized government-wide expert in matters related to his or her area of responsibility and is frequently called on to advise others concerning federal-state relationships, FDA policy, statutes, and regulations.
- Advises federal and state regulatory personnel on compliance matters related to human food safety and the regulation of animal food, which includes pet food.
- Identifies mechanisms to improve relationships and interoperability between FDA (headquarters and OHAFO Divisions) and state human and animal food programs.

- Advises other offices within ORA on procedures and methods for implementing new legislation or revising existing legislation and regulation and the impact to state human and animal food regulatory programs.
- Identifies training needs for federal, state, and local regulatory agencies, the human and animal food industry and consumers, and takes a leading role in the development and presentation of training program material that responds to the needs of federal and state regulators to support a comprehensive approach to animal food inspections, including training in foundational 2 of 20 comprehensive approach to animal food inspections, including training in foundational human and animal food programs and programs to support new food safety policy or regulations.

Supervisory Responsibilities: The CSO-NE position is not a supervisory role. The incumbent provides administrative direction only. The incumbent plans, designs, and executes work, including project management, with a wide latitude of independence. The incumbent responds directly to emerging projects, which may originate from CFSAN, ORA headquarters, the field, cooperating international, federal, or state agencies, or other sources.

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.
- 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.

To qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications.

Education Requirement: : The education must have been obtained at a college, university, or an accrediting body recognized by the Secretary, U.S. Department of Education at the time the degree was obtained. For more information please see: OPM Occupational Series Qualification Requirements.

Consumer Safety Series, 0696

Position requirement:

- This position requires the incumbent to have a current Driver's License.
- Able to travel up to 75% to various manufacturing sites across the US and abroad.
- Must meet physical demands of assignments conducting physical plant inspection. These assignments will require the climbing of staircases, working on wet floors, working in coolers, working in freezers, working in extreme heat, i.e., around retort cookers, and incidences when working with dangerous cleaning chemicals and unknown compounds.

Professional Experience:

- Experienced at the full performance level as an investigator in inspectional and investigative techniques in the human and animal food program area.
- Comprehensive knowledge of and skill in selecting, adapting, and applying investigative methods and negotiating techniques.
- Must be a recognized field technical expert/authority in terms of developing new approaches, methods, policies, procedures, and evidence, when situations are encountered that may result in regulatory action.
- Broad knowledge of a variety of various scientific and technical disciplines are necessary to carry out tasks related to the regulation of the food industry.
- Skill in planning and carrying out assignments, resolving most conflicts that arise, coordinating the work with others as necessary, and interpreting policy on own initiative in terms of established objectives. In some assignments, the employee also determines the approach to be taken and the methodology to be used. The employee keeps the supervisor informed of progress and potentially controversial matters.
- Demonstrated knowledge of written and verbal communication practices and principles to prepare and present written reports, findings, and recommendations; develop analyses that are used for presentations.

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:
If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

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

Applicants must submit a letter of interest addressing experience in the major duties and responsibilities of the position, a detailed current résumé, redacted SF-50 (for federal employees only), and transcripts (with foreign credentials evaluation if applicable) to the ORA Executive Recruitment Staffing Committee at: ORAExecutiveandScientificRecruitment@fda.hhs.gov. Please reference Consumer Safety Officer (National Expert) in the subject line.

Applications will be accepted May 17 through May 31, 2023. Applicant resumes may be shared with hiring official within the OHAFO with a similar job vacancy. Applicants can opt out of this process by annotating resume with “do not share”.

Announcement Contact

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

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FDA is an equal opportunity employer.