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 Dietary Supplement Programs (ODSP)
Division of Research and Evaluation (DRE)
Safety Evaluation Branch (SEB)
Branch Chief, (Supervisory Interdisiciplinary Scientist)

Application Period: August 18, 2023 – September 29, 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: Branch Chief, (Supervisory Interdisciplinary Scientist), Safety Evaluation Branch

Series: 0405 (Pharmacologist); or 0415 (Toxicologist)

Location(s): Remote

Salary: Starting at $132,368

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

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 (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 planning, developing, and administering policies and programs for protecting and promoting the public health by ensuring that the nation's food supply is safe, secure, sanitary, wholesome, and truthfully and otherwise properly labeled, and that cosmetic products are safe and truthfully and otherwise properly labeled.

Duties/Responsibilities

This position is located in the Department of Health and Human Services, Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition's (CFSAN), Office of Dietary Supplements Program (ODSP), Division of Research and Evaluation (DRE), Safety Evaluation Branch (SEB).

ODSP has the primary responsibility to implement the Federal Food, Drug, and Cosmetic Act as amended by Dietary Supplement Health and Education Act (DSHEA) of 1994, which ensures the safety and truthful labeling of dietary supplements. ODSP also provides technical and policy input to support FDA legislative, compliance, enforcement, and public affairs initiatives relating to dietary supplement oversight.

The SEB provides toxicology and risk assessment expertise on dietary ingredients and supplements to the Center and develops guidelines and establishes expectations for the safety of dietary ingredients and dietary supplements.

The Branch Chief, SEB provides overall expert guidance, leadership, and the scientific direction necessary for the effective accomplishment of the Branch's, Divisions, and Office's scientific goals and objectives pertaining to dietary supplements. Serves as a national and international expert authority within CFSAN and across FDA, by providing authoritative and specialized toxicology and risk assessment expertise in consulting on an array of safety and regulatory issues and matters related to dietary supplements.

- The Branch Chief is recognized as the Center, Agency-wide, national and international expert authority within CFSAN and across FDA, by providing authoritative and specialized toxicology and risk assessment expertise in consulting on an array of safety and regulatory issues and matters related to dietary supplements.

- Directs the technical and regulatory activities of the Branch, providing oversight for safety review for New Dietary Ingredient Notifications (NDINs), Safety Determination Memos , and related evaluations pertinent to dietary supplements.

- Provides direction to highly trained and skilled multidisciplinary regulatory scientists to ensure that all technical and scientific aspects of evaluations (e.g., toxicology, botany, clinical,) are addressed, that FDA's regulatory decisions are scientifically and statutorily

defensible, and that FDA's review is clearly documented in the administrative record and sufficient to demonstrate that dietary supplements are properly evaluated.

- Leads internal and intra-agency committees (e.g., Dietary Supplement Technical Advisory Group) and working groups, and is an FDA representative on external committees led by other federal and international public health organizations pertaining to dietary supplements and safety as well as testing procedures and compliance with appropriate guidelines and policies.

- Identifies and assesses emerging, standing, complex, or precedent-setting issues impacting Center procedures, policies, or resources in the areas of nutrition science and labeling related to dietary supplements that may have local, national, and international impact and evaluates and leads changes to our internal procedures, policies, and regulations, as needed.

- Manages and provides expert guidance on reviews of the evidence submitted with or related to the evaluation of citizen petitions and health claim petitions, which includes the review of all publicly available information pertaining to the relationship discussed in the petition.

- Ensures that all technical, scientific, and regulatory aspects of evaluations (e.g., current nutrition science, biochemistry, statistics, existing laws and regulations, etc.) of submissions or requests are addressed, that FDA's regulatory decisions are scientifically sound, and that FDA's review is clearly documented in the administrative record and sufficient to demonstrate that the regulatory action we are taking is based on sound science and appropriate regulatory considerations.

- Communicates with the regulated industry (e.g., food manufacturers) and consumer advocacy groups, other federal agencies, Congress, and international public health organizations to respond to inquiries, and to ensure support for FDA goals and objectives pertaining to nutrition and dietary supplement labeling.

- Serves as spokesperson for the Center during conferences and at seminars, workshops, advisory committees, and other public meetings on matters pertaining to our analysis of the scientific evidence and FDA laws, regulations, and policies related to nutrition labeling.

- Maintains contacts with scientists and officials outside the Agency and within FDA, as additional sources for identifying potential scientific research and regulatory activities and Agency resources.

Supervisory Responsibilities: This is a supervisory role. The Branch Chief serves as supervisor of record for the Safety Evaluation Branch. The supervisor provides specific technical and administrative direction 25 percent or more of the time to nine subordinate employees, as well as staff fellows, contractors, students, and other senior staff who are experts in the development of analytical methodology, in performing the work and functions of the organization. The Branch Chief assures implementation of goals and objectives of the Branch, including determination of Branch priorities that need additional emphasis, and planning for long range staffing needs. The Branch Chief directs development of data, provision of expertise, preparation of position and policy papers by subordinate staff, and execution of program activities within the Branch to ensure that the goals and priorities of the Division are met. The Branch Chief has review authority on work problems presented by Branch Staff and sign-off authority as designated by the Division Director and exercises significant responsibilities in advising the Division Director on scientific, regulatory, and policy issues pertinent to the safety assessment of dietary supplements. The Branch Chief conducts performance evaluation of staff, including resolving serious employee complaints and approving disciplinary actions and makes hiring selections for all positions within the Branch, as well as recommends awards or bonuses and changes in position classification. The Branch Chief also identifies and eliminates barriers to efficient completion of work product, improves business practices, and promotes team building and unit cohesiveness both within the Branch, between Branches in the Division, and the Office overall.

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:

Pharmacology Series, 0405:

Degree: major in an appropriate biological, medical, veterinary, or physical science, or in pharmacy that included at least 30 semester hours in chemistry and physiology and 12 semester hours in pharmacology.

Toxicology Series, 0415:

Degree: toxicology; or an appropriate discipline of the biological, medical, or veterinary sciences that included at least 30 semester hours in chemistry, biochemistry, or physiology, and 12 semester hours in toxicology.

For more information please see: OPM Occupational Series Qualification Requirements

Desired Education:
Our ideal candidate will possess:

- An Advanced Degree (i.e., doctoral level degree)in pharmacology or toxicology.

- One or more of the following achievements demonstrating that the individual is considered by recognized experts or peers in their field to be outstanding. The individual a) conducted original research published in peer-reviewed journals of high stature; b) received major prizes and awards (such as visiting professorships and named

lectureships) in recognition of original contributions to biomedical research; c) received invitations to speak at or chair major national or international meetings or symposia; d) elected to membership in professional societies of high stature; or e) meets other criteria demonstrating sufficient rigor or accomplishment in a relevant or closely related field.

Desired Professional Experience:
Our ideal candidate will possess:

- Expert level experience that demonstrates sound judgment, strong leadership abilities in a scientific or public health environment.
- Demonstrated experience communicating and effectively interacting with high level government officials, the scientific/academic communities, medical or health related organizations, members of congress or top level representatives of counterpart Federal agencies, foreign government, officials, CEO level and senior representatives from regulated industry, other research stakeholders, consumer organizations, and the general public.
- Demonstrated leadership competence and abilities to:
    - develop complex and basic program goals, and assure that agency goals and priorities are considered in carrying out and completing ISB's responsibilities;
    - direct and guide projects, including long-term and short-range planning;
    - establish objectives and priorities;
    - conduct periodic program assessments;
    - plan and direct the work of a multidisciplinary scientific staff.
- Extensive knowledge in dietary ingredients and dietary supplements.
- Practical knowledge of the application of FDA laws and regulations.
- Training, professional development, and outside activities that provide evidence of initiative, resourcefulness and potential for effective job performance such as invitations, presentations and international activities.
- Receipt of honors, awards or other recognition for performance or contributions based on managerial excellence.
- Professional leadership activities.
- Serves on the editorial board of a recognized journal or in a leadership role of a scientific/professional society or regulatory body.

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 reder 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

Applications will be accepted from all qualified internal and external applicants. Please send resume, letter of interest addressing your experience in the major duties and responsibilities of the position, SF-50 for current federal employees only, copy of all transcripts (with foreign credentials evaluation, if applicable) to CFSAN-CURES@fda.hhs.gov by closing date of the announcement, **September 29, 2023**, (as indicated within this posting and located at the top of this job announcement under application period). Please reference Job Reference ID: ***"ODSP Branch Chief, SEB"***

Announcement Contact

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

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FDA is an equal opportunity employer.