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 Nutrition and Food Labeling (ONFL)
Infant Formula and Medical Foods Staff (IFMFS)
Staff Director (Supervisory Physician)

Application Period: December 21, 2023 – January 22, 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: Staff Director, Supervisory Physician for Infant Formula and Medical Foods Staff

Series: AD-0602, Physician

Location(s): College Park, MD

Salary: Starting at $195,000

Work Schedule: Full Time

Cures Band(s): Band E

Full Performance Band Level: Band E

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 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

Infant Formula and Medical Foods provides technical knowledge and expertise in composition, nutrition, and safety of infant formulas set forth under the Infant Formula Act of 1980, and subsequent amendments. Manages and provides scientific review and analysis of infant formula submissions, petition dossiers, and inspection records as they are submitted in order to determine if the requirements for safety and nutritional adequacy have been met. Develops regulations, compliance policy, position papers, regulatory guidelines, guidance, and advisory opinions for matters within the scope of infant formula and medical foods. Provides expert advice to the Office Director, Center Director, other key officials and national and international bodies on infant nutrition and infant formula and medical foods initiatives and issues. Provides clinical and scientific expertise on the design and conduct of clinical trials for stakeholders, risk assessment, and adverse event reports. Provides training for and feedback to FDA Field investigators in order to strengthen FDA's oversight on issues related to infant formula and medical foods.

The incumbent serves as a Supervisory Physician in the Infant Formula and Medical Foods Staff of the Office of Nutrition and Food Labeling and is responsible for the following duties:

- Identifies, researches, anticipates developments and recommends action(s) that will have a direct impact on the regulatory programs and policy for infant formula and medical foods. Recommends FDA actions that can involve drafting of proposed regulations, strategy documents, policy statements, formal guidance, letters to regulated industry, or various combinations of these actions within the context of applicable laws, policies, and regulations. Reviews final proposals for new regulations, policy statements and guidance involving infant formula and medical foods. Provides expert advice and guidance to scientific leadership on infant nutrition and medical foods within FDA, for other government agencies, the regulated industry, academia, and international regulatory scientific organizations.
- Recommends FDA actions that can involve drafting of proposed regulations, strategy documents, policy statements, formal guidance, letters to regulated industry, or various combinations of these actions within the context of applicable laws, policies, and regulations. Provides leadership and technical assistance on legislation and feedback for international regulatory authorities.
- As a nationally and internationally recognized expert on infant formula, provides authoritative guidance on FDA positions and actions. Breaks new ground regarding FDA policies and procedures for industry, senior leadership, national and international organizations.
- Supervises a staff of nutritionists, chemists, consumer safety officers and other staff with technical training in the area of infant formula and medical foods.

- Develops, validates, and documents regulatory approaches to support the safe use of complex, novel ingredients in infant formula; provides leadership, including up-to-date knowledge regarding those ingredients that are bioactive. Where appropriate, the incumbent identifies areas of new science and proposes policy approaches and changes to address uncertainty or potential issues in novel safety assessments. Possesses the necessary leadership skills to develop standards of adequacy for the clinical and pre-clinical studies necessary to demonstrate that the quality factor requirements have been met.
- Integrates nutrition science into developing policies, including internal guidance and standards, for the evaluation of infant formula safety and nutritional adequacy and for medical foods consults and queries.
- Works with FDA biologists, chemists, toxicologists, consumer safety officers and other technical staff to provide updates on complex scientific and regulatory matters arising from controversial topics in infant nutrition. Provides FDA leadership and oversight as a supervisor in the management and review of the most highly complex submission materials for infant formulas and controversial queries for infant nutrition and medical foods. The highest level of skill is involved in reviewing novel infant formula ingredients and procedures, for scientific validity of data. Reviews novel FDA infant formula and nutrition proposals to ensure consistency in approach and application of infant stage-specific regulation and policy across centers. Reviews FDA infant formula and nutrition assessments to ensure consistency in approach and application of infant stage-specific regulation and policy across centers.
- Makes formal national and international presentations on the FDA's policies regarding infant formula review. Such presentations might include a discussion of current approaches to safety assessment, the type and amount of data needed to support the safety of infant formula products, and optimization of study protocols to assess the safety of food ingredients and constituents for infant developmental life stages.

Supervisory responsibilities: Supervises the Infant Formula and Medical Foods Team which includes nutritionists, chemists, consumer safety officers and other specially trained staff. 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 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 degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and

medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates.

AND

Graduate Training: In addition to a degree, a candidate must have had at least one year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the United States or Canada.

Desired Education: Our ideal candidate would have advanced training and board certification in neonatology or pediatrics.

Desired Professional Experience:

- Highest level experience communicating complex technical information in a clear way and works with staff at all levels of the organization and varying levels of domain expertise; excellent listening skills and a commitment to communicate in a very timely manner.
- Demonstrated ability in supervising and managing a team with specialized training.
- High level experience working independently, initiates own work, and also as a contributing, collaborative team member.
- Superior time management and organizational skills to effectively determine priorities and move work forward.
- Demonstrated superior ability to develop networks and build alliances; collaborates effectively across boundaries to build strategic relationships and achieve common goals.
- Readily identifies internal and external politics that impact the work of the organization. Perceives organizational and political reality and acts accordingly.
- Identifies and analyze problems; weighs relevance and accuracy of information; generates and evaluates alternative solution; develops key policy and regulatory 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

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

Submit resume or curriculum vitae, cover letter, and copy of all college transcripts and/or foreign education evaluation by the closing date as identified above to CFSAN-CURES@fda.hhs.gov and include the job reference ID: ***ONFL Staff Director, IFMFS***. 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 and include the job reference ID: ***ONFL Staff Director, IFMFS***.

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.

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