Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Food Safety & Nutrition (CFSAN)
Office of Nutrition and Food Labeling (ONFL)
Medical Officer for Critical Foods

Application Period: 03/27/2023 – 04/21/2023

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 Physician (Medical Officer) for Critical Foods

Series: AD-0602

Location(s): Various Locations

Salary: Starting at $180,000

Work Schedule: Full Time

Full Performance Band Level: Band D

Cures Band(s): Band D

Travel Requirements: Up to 25%

Bargaining Unit: 3591, National Treasury Employees Union

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.

Office of Nutrition and Food Labeling (ONFL) provides policy development and management of food and nutrition labeling, conventional foods, special nutritionals (including critical foods such as infant formula and medical foods), and associated educational initiatives. Develops regulations, compliance policy, position papers, regulatory guidelines, and advisory opinions for matters within the scope of the responsibility of the Office. Provides expert advice to the Center Director, other key officials, and directs major Food and Drug Administration (FDA) and Department nutrition and food labeling initiatives. Manages and provides scientific review on issues related to infant formula and medical foods including petitions and notifications and provides advice to key FDA components as well as international bodies. Provides clinical and scientific expertise on the design and conduct of clinical trials, risk assessment, adverse event reports, and educational initiatives related to infant formula and medical foods.

Duties/Responsibilities

This position serves as a professional Physician who oversees, manages, organizes, and directs all operations, program segments, functions, and activities of the infant formula and medical foods staff, as carried out by the team leader and staff. The Physician applies his/her professional expertise in pediatrics and/or neonatology, and technical skills/training with knowledge of administrative and program management principles in order to carry out the mission of the Staff. This includes addressing and solving unusual and often precedent-setting problems associated with infant formula and medical foods.

The Physician seeks and develops the most cost effective and fiscally responsible methods to conduct these programs and solve problems.

Initiates decision-making processes and manages the preparation of policy and regulatory documents, and participates fully in discussions and decisions concerning Office and Center plans, programs, and activities, both in strategic planning and in the actual determination, allocation, and administration of infant formula and medical foods programs.

Identifies and coordinates internal (CFSAN/FDA) and external subject matter experts to ensure that the best available science is applied to Agency decision making.

Develops and implements staff policies and plans, decides critical issues, and provides expert advice and counsel concerning approaches and options that are sound and feasible in relation to Office and Center scientific, policy, and regulatory goals, objectives, and Federal budgetary and economic realities.

Evaluates scientific, budget, fiscal and administrative controls to manage Staff programs and services, and develops and makes recommendations for the enhancement and improvement of the mission and functions of the Staff.

Represents Staff; Office, and the Center in negotiations with individuals representing organization such as the Congress, other Federal Agencies; State, local, and foreign governments; the regulated industry; professional and industry organizations; and public interest groups.

Provides advice on all matters relating to infant formula and medical foods to the Office Director and to senior officials within FDA, including the Commissioner of Food and Drugs.

Manages the preparation, clearance, and finalization of Staff responses to inquiries covering regulatory policy, clinical, and scientific aspects of the infant formula and medical foods programs, and responses to infant formula notifications.

Implements new laws and regulations that impact its mission. This includes responsibility for the initiation and implementation of new policies, systems, procedures, and organizational structures.

Medical/Clinician Evaluation

- Monitors and medically evaluates adverse events and other sources for signals. related to the safety of critical foods, which include infant formula and medical food products.
- Coordinates and provides medical and scientific expertise in the risk assessment of infant formula and medical foods to assist the Office Director and other key staff on infant formula and medical foods policy issues and other related issues; provides clinical scientific responses to petitions, initiatives, and related infant formula and medical food activities.
- Coordinates and participates in advisory committee activities related to infant formula and medical foods.
- Participates in development of outreach programs and messages that provide information to consumers.
- Evaluates scientific, medical, and clinical rationale and data submitted in support of new and/or reformulated, infant formula, including use of new ingredients and adverse event-related outcome data for infants.
- Serves as member of the Center-wide medical officer team in the review and development of Health Hazard Evaluations (HHEs) to determine risk for all contaminated or mislabeled critical food products, including infant formula and medical foods.

Regulations and Review

- Assists in developing policies, position papers, and advisory opinions on issues related to infant formula and medical foods. Provides assistance to Federal and State agencies and industry concerning infant formula and medical food requirements
- Responsible for promulgation and amendment of regulations related to Good Manufacturing Practices (GMPs) and Quality Factors for infant formula.
- With the assistance of the team lead, oversees the review of and response to notifications for infant formula.
- Provides teclmical comment and support on issues relating to infant formula and medical food safety, and nutrient bioavailability for national and international efforts.
- Prepares written responses to consumer correspondence
- Oversees the evaluation of infant formula composition, scientific rationale, and data submitted in support of new and/or reformulated infant formula, including use of new ingredients, and nutrient bioavailability.

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 required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

Education Requirement: Physician Series, 0602

Degree: Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent from a school in the United States or Canada. This degree must have been accredited by the Council on Medical Education of the American Medical Association (external link); Association of American Medical Colleges (external link); Liaison Committee on Medical Education (external link); Commission on Osteopathic College Accreditation of the American Osteopathic Association (external link), or an accrediting body recognized by the U.S. Department of Education (external link) at the time the degree was obtained.

OR

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 (external link), a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination.

AND

Licensure: For all grade levels and positions, applicants must possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

AND

Graduate Training: Subsequent to obtaining a Doctor of Medicine or Doctor of Osteopathic Medicine degree, a candidate must have had at least 1 year of supervised experience providing direct service in a clinical setting, i.e., a 1-year internship or the first year of a residency program in a hospital or an institution accredited for such training. 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. Descriptions of such programs are described below.

An internship program involves broadly based clinical practice in which physicians acquire experience in treating a variety of medical problems under supervision (e.g., internal medicine, surgery, general practice, obstetrics-gynecology, and pediatrics). Such programs are in hospitals or other institutions accredited for internship training by a recognized body of the Accreditation Council for Graduate Medical Education (ACGME) (external link).

A residency program involves training in a specialized field of medicine in a hospital or an institution accredited for training in the specialty by a recognized body of the American Medical Association (external link), (AMA) or Accreditation Council for Graduate Medical Education (ACGME) (external link).

A fellowship program involves advanced training (beyond residency training) in a given medical specialty in either a clinical or research setting in a hospital, or an institution accredited in the United States for such training.

Professional Experience: Seeking experience with infant health and nutrition, nutritional needs of healthy infants and infants with unique medical requirements, and the evaluation of clinical adverse events and clinical studies.

Desired Professional Experience:

- Experience in developing policies, position papers, and advisory opinions on issues related to infant formula and medical foods.
- Expertise in providing assistance to Federal and State agencies, and industry concerning infant formula and medical foods.
- Experience in reviewing and responding to infant formula submissions.
- Experience providing technical comment and support on issues relating to infant formula and medical food safety, for federal national and international efforts.
- Expertise in developing written responses to consumer and stakeholder correspondence.
- Experience in reviewing infant formula composition, scientific rationale, and data submitted in support of new infant formulas, including use of new ingredients.
- Competitive candidates will have minimum of 5 years of advanced experience in their specialty.

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: Background Investigation/Security Clearance Requirements: A background investigation is required. All employees must pass a security background 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. 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.

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

Applications will be accepted from all qualified internal and external applicants. Please send letter of interest addressing your experience in the major duties and responsibilities of the position, SF-50 for current federal employees only, transcript (with foreign credentials evaluation, if applicable) to CFSANExecutiveRecruitment@fda.hhs.gov by 04/21/2023. For questions, please contact CFSANExecutiveRecruitment@fda.hhs.gov.

Announcement Contact

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