

Title 21 Vacancy Announcement Department of Health and Human Services (HHS) Food and Drug Administration (FDA) Office of the Commissioner

Application Period: 2/28/2023-3/31/2023

<u>Area of Consideration:</u> 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.

<u>Position:</u> Deputy Commissioner for Human Foods

Series: This position can be filled in a variety of series to include 301, 601, 602 or 701 series

Location(s): Silver Spring, MD

Work Schedule: Full Time

Starting at \$301,825

Cures Band(s): Band I

Full Performance Band Level: Band I

Travel Requirements: 25%

<u>Relocation Expenses Reimbursement:</u> 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: <u>21st Century Cures Act</u> 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.

Functional Duties and Responsibilities

The Food and Drug Administration (FDA) is a Federal scientific regulatory agency with the legislated responsibility to protect the public health of the Nation's consumers. The Food and

Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

FDA's programs are national in scope and effect, and its activities directly affect and heavily impact upon multi-billion-dollar industries, in addition to protecting the public health of hundreds of millions of American consumers.

As Deputy Commissioner for Human Foods, the incumbent reports directly to the Commissioner and serves as a clear line of authority over the entire Human Foods portfolio which presently include the Center for Food Safety and Applied Nutrition (CFSAN), the Office of Food Policy & Response, and certain human foods-related components of the Office of Regulatory Affairs (ORA). Going forward, these components will be realigned into a unified Human Foods Program, and this position will be realigned to this organization in the future and be its executive leader. The Deputy Commissioner serves as the principal advisor to the Commissioner of Food and Drugs in matters relating to policy initiatives that involve human food, including safety, innovation, and nutrition programs. The incumbent exercises executive leadership and sets the strategic direction and operations of the Agency's Human Foods Program and serves as its advocate internally and externally. The incumbent plans, organizes, directs, staffs, coordinates, controls and evaluates the Agency's human foods program to achieve the goals and mission of FDA with maximum effectiveness, including resource allocation, risk prioritization, and strategy for the deployment of inspectional and field resources dedicated to the human foods program.

Duties/Responsibilities

- Provides leadership for organizational change anticipated in unifying several human foods organizations and functions into a unified Human Foods Program and leads efforts to further define the operational and decision rights of the new structure and its relationship with human foods activities in ORA and CVM in partnership with leadership in these organizations.
- Directs cultural transformation in the Human Foods Program and ORA's human foods workforce and set priorities and goals for training programs related to human foods.
 Develops and implements a strategy to manage change and effectively improve and monitor the environment for cultural change. Promotes innovation and encourages

informed risk-taking to take novel, precedent-setting actions to promote public health to address emerging food challenges and opportunities. Encourages innovative approaches to policy and science as part of stakeholder dialogue. Engages routinely and transparently with external community. Fosters regulatory decision-making in scientific evidence and FDA's legal framework. Establishes program for assessment and monitoring of impacts of Human Foods programs and policies.

- Develops and provides leadership for new policy, legislative, partnership, and regulatory operations for the Human Foods program. Represents the Agency, at the direction of the Commissioner, in Congressional engagements on the Human Foods Program.
- As designated by the Commissioner, represents the Agency in meetings and conferences
 and establishes and maintains effective relationships with top level FDA and HHS
 officials, national/international industry representatives, Members of Congress,
 counterparts from other Federal, State and local government agencies, foreign
 government representatives, academia, consumer and other groups to secure,
 exchange and provide information concerning human food policy, science, regulatory,
 and innovation issues. The incumbent is authorized to speak for the Commissioner and
 to commit the Agency to courses of action on these matters.
- Provides executive leadership to all programs under his/her/their jurisdiction. This
 includes exercising on behalf of the Commissioner, all legal authorities related to human
 food, including safety, innovation, and nutrition, that the Commissioner is empowered
 to exercise under the Federal Food, Drug, and Cosmetic Act, as amended, the Public
 Health Service Act, and other applicable laws. On behalf of the Commissioner, provides
 executive leadership in efforts to coordinate cross-cutting policy activities and
 associated external engagement activities related to human food, including safety,
 innovation, and nutrition.
- Directs work of Human Foods Program and ORA human food activities to develop innovative collaborations and positive working relationships with external partners and stakeholders, both domestically and internationally, serving as an outward-facing ambassador for the Agency's work.

Supervisory Responsibilities: The incumbent of this position is directly responsible to, and functions under the broad administrative direction of, the Commissioner of Food and Drugs. Incumbent is expected to work with an exceptional degree of independence and initiative to reach conclusions and solve problems. Technical advice and recommendations are normally accepted without significant changes. Work is reviewed for accomplishment of broad objectives.

This position is designated as an SES Equivalent position and is covered under the FDA Title 21 Executive Performance Management System and identified as a public filing position for ethics purposes.

Organizational Management: Manages an organization, including overseeing the Center for Food Safety and Applied Nutrition and ORA human foods components.

Program Management: Runs a program reporting directly to the Commissioner and is responsible for overseeing the human foods-related programs and functions presently within the Center for Food Safety and Applied Nutrition, Office of Food Policy & Response, and certain ORA components, which are proposed to be unified into a new Human Foods Program. Identifies outcomes needed to achieve mission goals. Establishes and directs program outcomes for the Agency's Human Foods Program. Establishes and directs organizational objectives that encompasses the Agency's public health mission, operational and human capital strategies.

Resource Management: Possesses highest resource authority in the Human Foods Program. Allocates resources according to mission alignment. Delegates resource authority as appropriate. Serves as accountable official for resource management and reporting.

Personnel Performance Management: Counsels and rates immediate subordinates.

Human Capital Management: Identifies organizational capabilities needed to achieve Program mission goals.

employment opportunity (EEO) by taking positive steps to assure the accomplishment of affirmative action objectives and by adhering to non-discriminatory employee practices in regard to 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. Specifically, as a manager, the incumbent initiates nondiscriminatory practices and affirmative action for the Program in the following: (1) merit promotion of employees and recruitment and hiring; (2) fair treatment of all employees; (3) encouragement and recognition of employees' achievements; (4) career development of employees; and (5) full utilization of their skills.

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 <u>OPM Qualification Standards</u> 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.

Professional Qualifications:

- Strong background in food safety and nutrition with 15 or more years of senior technical and policy experience. Backgrounds in areas other than food safety and nutrition but relevant to leading a public health food safety and nutrition regulatory organization will be considered.
- In-depth knowledge of the Federal authorities, policies, scientific and regulatory programs as they relate to human foods.
- Talent for building partnerships and coalitions with stakeholders in public and private arenas.
- Demonstrated executive-level leadership experience directing large diverse and multidisciplinary organizations, including scientific and regulatory organizations.
- Demonstrated ability to successfully manage vast operations in a national or global organization.
- Expertise in setting public-health goals and priorities based on risk prioritization and desired public health outcomes.
- Expertise in establishing decision-making frameworks that balance public health, legal, regulatory, scientific, and policy considerations.
- Talent for leading and building cultural and organizational transformation efforts.

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:

<u>Additional Info:</u> This position is being filled under the 21st Century CURES Authority, under Band I (Executive level). Applicants applying for this position do *not* need to hold an active medical license.

Veterinary Medical Science Series, 0701

Degree: Doctor of Veterinary Medicine (DVM) or equivalent degree, i.e., Veterinary Medical

Doctor (VMD), obtained at a school or college of veterinary medicine accredited by the American Veterinary Medical Association Council on Education (AVMA).

General Health Sciences Series, 0601

Degree: Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the <u>U.S.</u>

<u>Department of Education</u> at the time the degree was obtained.

Public Health Program Specialist 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 <u>Council on Medical Education of the American Medical Association</u>; <u>Association of American Medical Colleges</u>; <u>Liaison Committee on Medical Education</u>; <u>Commission on Osteopathic College Accreditation of the American Osteopathic Association</u>, or an accrediting body recognized by the <u>U.S. Department of Education</u> at the time the degree was obtained.

This position may also be filled in the following series: 301- Miscellaneous Administration & Program Series. There is no education requirement for this series, but experience related to the position will be evaluated.

Education Transcripts

<u>SUBMITTING YOUR TRANSCRIPTS:</u> 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.

<u>FOREIGN EDUCATION:</u> 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>U.S. Department of Education website for Foreign Education Evaluation</u>.

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 is required.
- Ethics Clearance is 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.
- This position is designated as an SES Equivalent position.

Drug Impact Statement for Top Secret/SCI Security Clearance

This position is special-sensitive and requires the incumbent to have access to highly classified data, documents, facilities and/or materials related to national security, thus demanding the highest degree of public trust, and requiring the incumbent to possess and maintain a Top Secret/SCI security clearance. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions leading to the disclosure of highly sensitive, top-secret information. Therefore, this is a Testing Designated Position, and the incumbent is subject to testing for drug usage in accordance with the DHHS plan for a Drug Free Workplace.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements:

This position requires a Top-Secret security clearance, and the incumbent has access to documents and facilities related to national security. Drug usage could impair the reliability, stability, and judgment of the incumbent which could undermine public confidence in the agency. Drug dependency would create the possibility of coercion and irresponsible actions

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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.

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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 <u>disability employment and reasonable accommodations</u> or <u>how to contact an agency</u>.

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 with cover letter by **11:59pm on 3/31/2023** to: CuresExecutives@fda.hhs.gov. Please reference Job ID in subject line of email: **OC-OHF-2023-01**

Announcement Contact

For questions, please contact <u>CuresExecutives@fda.hhs.gov</u>. Please reference Job Reference ID in subject line of email: **OC-OHF-2023-01**

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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