Title 21 Vacancy Announcement
Office Director
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Veterinary Medicine (CVM)
Office of Generic Animal Drugs (OGAD)

Application Period: November 22,2024- December 6, 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: Office Director

Series: AD-0701 & 0401

Location(s): Rockville, Maryland.

Salary: Starting at $213,491.00

Work Schedule: Full Time

Title 21 Pay Table & Band: Pay Table 4, Band G

Full Performance Band Level: Band G

Travel Requirements: up to 25%

Bargaining Unit: 8888

Relocation Expenses Reimbursement: Will not be paid.

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 Veterinary Medicine (CVM) is to protect and promote human and animal health from a One Health perspective. CVM ensures the safety of the American food supply, the safety of animal food and devices, and the safety and effectiveness of animal drugs. Specifically, CVM evaluates new animal drug applications for safety and effectiveness and manufacturing quality; monitors animal drugs, animal foods, and animal devices for safety and

takes appropriate action to mitigate unsafe or violative products on the market; evaluates animal food additives for safety and utility; conducts applied research to further scientific understanding and support data-based decision making to protect human and animal health; works to prevent and respond to human and animal health emergencies; and develops and implements policies to combat antimicrobial resistance. As a high-performance organization within the FDA, CVM strives for excellence, innovation, and leadership across all operations, occupations, and grade levels.

The Office of Generic Animal Drugs (OGAD) evaluates bioequivalence of generic new animal drugs in pharmaceutical dosage forms and animal feeds; including evaluation of the safety aspects of drug residues remaining in food produced for human consumption from animals administered generic drugs. Reviews and determines the adequacy of information submitted in support of proposed use of generic new animal drugs, recommends to the Center Director appropriate action on new generic animal drug applications, and acts on generic investigational new animal drug (JINAD) notices of exemption and authorization requests.

Duties/Responsibilities

The Director, Office of Generic Animal Drugs (OGAD), is the principal advisor to the Center Director, Center for Veterinary Medicine (CVM), providing expert-level administrative, scientific, and regulatory authority for CVM on matters related to pre-market review of generic animal drugs. Assists the Center Director on security intelligence matters involving OGAD; accessing classified information in written and/or electronic formats and requiring Top Secret Clearance. The incumbent provides scientific, administrative, and regulatory leadership and direction through subordinate division directors for FDA's pre-market generic animal drug regulatory program activities. The Office Director oversees the work of the Office with specific duties as follows:

- Coordinates CVM’s regulatory pre-market generic animal drug review program to ensure the safety, effectiveness, and manufacturing quality of approved generic animal drugs. Specifically, is responsible for (a)review of organizational structure, functions, responsibilities and work assignments to assure the effective,efficient, and economical use of scientific, professional and technical staff; (b) evaluation of pre-market generic animal drug review policies and procedures to increase effectiveness, efficiencies and resource savings in program areas; (c) strategic planning to ensure alignment of the Office’s Strategic Plan with those of the Center, FDA, and HHS; and (d) oversight of the development of new regulations, policies, guidance and procedures impacting pre-market generic animal drug review program requirements.
- Serves as a nationally recognized authority, expert, and leader in regulatory and science policy aspects of premarket generic animal drug review and, as such, provides technical and regulatory guidance for the Office’s generic animal drug review programs. Provides authoritative advice and information on regulatory evaluation of generic animal drugs to the Center Director, other Government agencies and external organizations.
- Applies a broad knowledge of regulatory aspects of pre-market generic animal drug review and an intimate understanding of the provisions, limitations and practical applications of FDA’s enabling legislation and the Code of Federal Regulations. Reviews and evaluates project proposals and plans in terms of soundness of scientific, technical, legal reasoning, sufficiency of project proposals, relative priorities, availability of resources and anticipated results.

Implements changes in structure that may be needed to meet shifts in program goals or to accomplish new requirements imposed by legislation and FDA policy or regulations.

- Develops broad, complex programs that are critical to the organization. The incumbent directs the preparation of analyses of the impact of proposed changes to Agency laws and regulations which affect functions, program segment(s), and activities of the Office necessary to implement new legislation or regulations and develops various scenarios for dealing with expansion or contraction of Office functions, program segment(s), and activities. Directs the development and implementation of new laws, regulations, guidance, and policies which impact the mission of the Office to evaluate abbreviated new animal drug applications and ensure safety, effectiveness, and manufacturing quality of generic animal drugs.
- Provides technical and regulatory leadership to scientific/professional and support personnel engaged in executing FDA's broad national regulatory programs and activities as required by statute or FDA published regulations. This includes addressing and solving unusual and often precedent setting problems and assisting the regulatory review segments. Reviews and evaluates Center programs and activities associated with generic animal drug review in terms of achieving program goals and objectives and accomplishing legislated responsibilities.
- Represents the Office in dealings with other Federal agencies; State, local, and foreign governments; Congress; the regulated industry; professional and industry organizations; and public interest groups and in other matters dealing with Agency policy and programs as it relates to generic animal drugs. Builds and maintains collaborative network of scientists, regulators, and professionals who are internal and external to the FDA (e.g., other Federal Agencies, state-level governments, and/or others who share mutual concerns and/or regulatory responsibility for ensuring the safety, effectiveness, and quality of generic animal drugs.
- Manages resources to achieve the performance goals outlined within the Animal Generic Drug User Fee Act (AGDUFA).

Supervisory Responsibilities:
Supervisor provides occupational specific technical and administrative direction 25 percent or more of the time to three or more subordinate employees performing the work and functions of the organization. 1) Obtains resources and identifies strategic objectives for the organization. 2) 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. 3) Recommends employee promotions and recognition; approves leave; implements performance modifications and takes corrective actions as appropriate. 4) 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. 5) 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:

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). The AVMA web site, http://www.avma.org(external link), has a listing of all AVMA-accredited veterinary medical schools.

OR

Graduates of foreign veterinary medical schools that are not accredited by the AVMA Council on Education (Refer to AVMA web site, http://www.avma.org (external link) for information.

Series: 0401
Degree: biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position.

OR

Combination of education and experience: Courses equivalent to a major, as shown in A above, plus appropriate experience or additional education.

For more information please see: OPM Occupational Series Qualification Requirements

Desired Professional Experience:

- Advanced education, such as D.V.M., Ph.D., M.S. and/or board certification in relevant scientific discipline is encouraged.
- Knowledge of and experience working with federal regulatory programs and the Federal Food, Drug, and Cosmetic (FD&C) Act.
- Knowledge and experience in FDA regulatory standards and an understanding of the laws and regulations pertinent to the generic new animal drug approval process.
- Experience with the conduct of laboratory research and application of the scientific method approach to conducting and evaluating experiments.
- Demonstrated ability to develop networks and build alliances; collaborates across boundaries to build strategic relationships and achieve common goals.
- Demonstrated leadership skills in championing values that includes but not limited to honesty and integrity, creativity and innovation, commitment and accountability, delegation, and empowerment, and fully embracing a vision and purpose of the organization in leading a highly technical team.
- Communicator who can drive collaboration and teamwork, empower staff, and is committed to CVM/FDA's Public Health mission of protecting human and animal health; and has skill in written and verbal communications to prepare written documents and findings and to present finding and conduct briefings.
- Demonstrated skill in identifying and analyzing problems; generating alternative solutions and make 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: Public Trust/ High Risk

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

How to Apply: Submit resume or curriculum vitae with cover letter by **December 6, 2024** to: CVMOpportunities@fda.hhs.gov. For questions, please contact CVMOpportunities@fda.hhs.gov. Please reference Job Reference ID: Title 21-CVM/OGAD-Office Director

Announcement Contact

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

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FDA is an equal opportunity employer.