Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Medical Products and Tobacco Operations (OMPTO)
Office of Pharmaceutical Quality Operations (OPQO)
Division of Pharmaceutical Quality Operations III (DPQOIII)
Pharmaceutical Quality Investigations Branch I (PQIB)
Director of Investigations Branch (DIB)

Application Period: October 11, 2022 through October 25, 2022

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: Director of Investigations Branch (DIB)

Series: AD-0696

Location(s): ORA office duty stations in Chicago District; Cincinnati District; Detroit District; Kansas City District; Minneapolis District.

Salary: Starting at $126,233 (Pay Table 1)

Work Schedule: Full Time

Full Performance Band Level: Band D

Cures Band(s): Band D

Travel Requirements: Up to 25% travel required

Bargaining Unit: This is a non-bargaining unit position

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) is a Federal, science-based regulatory agency with the legislated responsibility to promote and protect the health of the nation's 265 million consumers, in their use of foods, food additives, human and animal drugs, biological products, cosmetics, medical devices, tobacco products and radiation-emitting products and substances. FDA's programs are global in scope and effect, and its activities directly affect and heavily impact on multi-billion-dollar industries, assuring honest and fair dealing in the marketplace,

while protecting the public health.

To view our ORA Vision, Mission, and Values please visit:
https://www.fda.gov/about-fda/office-regulatory-affairs/ora-vision-mission-and-values.

FDA's Office of Regulatory Affairs (ORA) is the lead office for all agency regulatory activities. ORA supports the six FDA product centers by inspecting regulated products and manufacturers, conducting sample analyses on regulated products and reviewing imported products offered for entry into the United States. In addition to executing its mission through its federal workforce, ORA also works with the FDA Centers, who develop FDA wide policy on compliance and enforcement and ORA executes the annual commodity work plans. Over 5,000 ORA employees located in district offices, resident posts and laboratories, strategically located throughout the United States perform inspections and investigations (including criminal investigations), wharf exams, sample collections and analyses, and carry out enforcement activities, education and outreach directly to consumers, industry representatives, importers and shippers as well as other stakeholders across the nation. ORA also works with its federal, state, local, tribal, territorial and foreign counterparts to further the agency's mission. ORA is led by the Associate Commissioner for Regulatory Affairs (ACRA).

The Office of Pharmaceutical Quality Operations (OPQO) is specialized to help protect and promote the safety and quality of human and animal products. This program, within the Office of Medical Products and Tobacco Operations (OMPTO) in the ORA, provides advice and counsel to ORA and FDA leaders regarding pharmaceutical products, field operations, and emergency response activities. OPQO collaborates with the agency's Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM) on all FDA-regulated pharmaceutical and biopharmaceutical products.

Duties/Responsibilities

The position serves as the Director of the Investigations Branch (DIB) in an ORA program Division, Office of Medical Products and Tobacco (OMPTO) who directs the formulation and recommendation of plans and participates with the Program Division Director in the establishment of goals and priorities in his/her assigned area. Additional responsibilities include:

- Responsible for the interpretation of established operating policies and procedures dealing with all inspection and investigation operations conducted by the Program area in the commodity area of Pharmaceuticals.
- Provides oversight and technical guidance to programs and activities, which may include, but are not limited to conducting investigations and inspections of human and animal drugs, providing inspectional support in pharmaceutical programs for which the Agency has responsibility; conducting product recall and emergency response activities, often in collaboration with other federal or state partners; conducting evaluations to measure program effectiveness and accomplishments against the field work plan

objectives; and providing assistance to State and localities in the event of a national disaster or other emergency requiring Agency assistance.

- Develops and maintains liaison and cooperative relationships with HHS operating divisions and with other federal agencies and congressional representatives operating within the assignment area(s) and with a variety of national public health organizations, academic institutions, and state and local health departments. The DIB exercises significant responsibilities in dealing with these officials, with delegated responsibility to represent ORA in Agency meetings and conferences.
- Develops and maintains effective communication with the regulated industry, consumer groups and the general public to foster understanding of the Agency's programs activities and regulations.
- Fully participates in all phases of Program planning and policy formulation, collaborating with senior management in developing substantive programs and plans that permit optimum accomplishment of program responsibilities within assigned resources.
- Determines overall office policies and approaches to be followed to achieve the mission of the Agency consistent with ORA established policies and procedures.
- Maintains continuous crucial review of all policy and project objectives of the office and ensures that overall program plans are carried out as efficiently and effectively as possible with maximum utilization of resources.

Supervisory Responsibilities:

The incumbent directs and manages operations within the assigned office, providing leadership and guidance to first-line supervisors and subordinate employees engaged in inspections and investigations of regulated industries and implementation of policy for the pharmaceutical program area(s). Responsibilities include:

- Planning and assigning work to be accomplished by subordinate supervisors and employees; defining technical work requirements and milestones; setting priorities through the subordinate supervisors based upon workload and abilities; and ensuring reasonable equity among subordinate components concerning performance standards, rating techniques, and assessment of subordinates and adequacy of contractors.
- The incumbent interviews and selects candidates for positions, promotions, and reassignments; makes recommendations pertaining to employee awards; approves/ disapproves leave; hears and resolves complaints from employees; effects disciplinary measures; and identifies developmental and training needs for employees.
- Plans organizational structures, staffing needs, and training etc., for the assigned office; obtains resources and identifies strategic objectives for the organization; initiates or participates in review and improvement of work methods, organizational features, and the structuring of positions to achieve optimum efficiency; deals with personnel management policy matters affecting office operations, with personnel actions affecting employees, and with personnel-related actions having program impact.
- Evaluates activities to determine which program areas are most productive, which are

worthy of support in reaching goals, and which should be emphasized or curtailed.
- Makes administrative management decisions regarding major changes in the office's internal work processes and resources distribution to improve operating efficiency and equipment utilization and reduce backlogs.

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.
- This position requires the incumbent have the following: current Driver's License.
- This position requires up to 25% travel.

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: The education must have been obtained at a college, university, or an accrediting body recognized by the Secretary, U.S. Department of Education at the time the degree was obtained. For more information please see: OPM Occupational Series Qualification Requirements.

Consumer Safety Series, 0696

Professional Experience: To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the grade level of the position. Examples of specialized experience include independently carrying out routine investigations, inspections, entry review, filer audits and sampling; documenting and organizing evidence, data, and other information to support violations, and assisting higher level employees in the review and evaluation of inspection reports of products or establishments.

Desired Education: Advanced degree

Desired Professional Experience:

- Advanced knowledge of Medical Products, Pharmaceutical and/or Tobacco
- Supervisory experience in developing and implementing an organizational vision for a large complex and diverse organization that integrates broad program goals, priorities, and balances change and continuity
- Experience establishing organizational policy, including the implementation of new legislative authorities or other significant mandates
- An advanced degree in law, science, public health, management, or other related field from an accredited college/university
- Experience collaborating with top level officials within an organization as well as officials from federal, state or city governments, professional health organizations, the regulated industry, consumer organizations, etc. to accomplish goals
- Experience formulating and establishing strategies and influencing strategy and policy relating to compliance, enforcement or imported pharmaceutical activities.

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: If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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 applicants. Please send letter of interest addressing your experience in the major duties and responsibilities of the position, resume and bibliography, redacted SF-50 for current federal employees only, transcript (with foreign credentials evaluation, if applicable) to the ORA Executive Recruitment and Scientific Staffing Committee, oraexecutiveandscientificrecruitment@fda.hhs.gov. Applications will be accepted through October 25, 2022. Candidate resumes may be shared with hiring official within the OMPTO with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. Please reference Job Reference ID: OPQO DPQO3 PQIB DIB

Announcement Contact

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

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

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