TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
Office of Regulatory Science (ORS)
Office of Medical Products, Tobacco, and Specialty Laboratory Operations (OMPTSLO)

Position: Senior Science Advisor

Series: 401, 403, 1320

Location(s): Cincinnati, OH

Travel Requirements: 25%

Application Period: September 4, 2020 to September 18, 2020

Salary: Title 21 (AD) Band E, starting at $142,701

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

Special Notes: This position is being filled under an excepted 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 the authority.

Additional information on 21st Century Cures Act can be found here.

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.

In the Office of Regulatory Affairs (ORA), we work in a range of program areas and locations, with 227 offices and 13 laboratories throughout the nation or around the world. Our employees conduct inspections, investigate criminal violations, analyze lab samples, provide administrative

services, and much more. Be a part of ensuring that the thousands of products we use every day are safe and effective.

ORA is the lead office for all Agency field activities. ORA conducts inspections and investigations (civil and criminal) of regulated products and manufacturers, conducts sample analysis of regulated products and reviews imported products offered for entry into the United States. In pursuit of its mission, ORA also works with its state, local, tribal, territorial and foreign counterparts. ORA is led by the Associate Commissioner for Regulatory Affairs (ACRA) who directs and evaluates the overall management and capabilities of the Agency's field organization.

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

The Office of Regulatory Science (ORS) provides a focal point for all aspects of ORA Field Laboratories and serves as the Office of Regulatory Affairs' headquarters for scientific and technical staff. ORS foster partnerships, within and outside of the Food and Drug Administration and provides convincing and prevailing scientific research and analytical basis for regulatory decisions to protect and promote public health.

Office of Medical Products, Tobacco, and Specialty Laboratory Operations (OMPTSLO) provides oversight on scientific issues and laboratory analysis related to pharmaceuticals, tobacco, medical devices, radiochemistry, and forensic chemistry to eight laboratories and associated programmatic staff. This Office works with appropriate Centers and other stakeholders to establish and execute strategic and tactical plans for the effective use of ORA science resources.

Position Summary:

As Senior Science Advisor for the Associate Director, OMPTSLO (AD-OMPTSLO), the incumbent provides scientific vision and leadership to ORA senior staff and represents ORA at the highest level regarding scientific policy and process. A major focus of the position will be ORA's MPTS laboratories. The incumbent in this position, through their training and experience will recommend to the AD-MPTSLO, Director ORS, ACRA and other ORA senior leadership, additions and/or modifications to existing scientific programs to meet Agency, public health and regulatory scientific mission priorities.

Supervisory responsibilities: Provides scientific leadership and direction for ORA/ORS in the areas of pharmaceuticals, medical devices, rad health, tobacco, and forensic support related to criminal investigations, in coordination with the Super Office Director and assists in identifying scientific competency and resource gaps.

Duties/Responsibilities:

Provides scientific leadership and managerial direction to professional personnel engaged in a

variety of substantive activities related to the planning, development, execution and coordination of OMPTSLO's and ORA's scientific program policies and activities.

Provides ORA-wide focus to ensure a strong public health and scientific underpinning to ORA policies and programs, making recommendations in terms of their scientific merit, soundness of reasoning, relative priorities, availability of resources, and anticipated results.

As a spokesperson for ORA Regulatory Science, the incumbent will represent ORA/ORS/OMPTSLO as the senior scientist with both internal and external constituencies. Serves as the AD-OMPTSLO's scientific/laboratory representative on various task forces and committees and in this capacity meets and deals with officials of industry; academia; consumer groups; public health partners, the Centers, the Department; the Administration; and other federal, state, local, and foreign counterpart governmental authorities.

Analyzes and assesses the impact of new laws, regulations, and other Congressional, Administration, Departmental or Agency initiatives on ORS/ORA laboratory resource requirements including number and type positions, expertise needed, training required, and optimal equipment. Furnishes expert advice and comments on scientific matters related to existing and proposed policies, programs, regulations, proposed legislation, and legislative strategy.

Participates in identifying FDA/ORA/ORS/OMPTSLO needs in terms of national goals and in developing the direction of scientific programs and policies to ensure that Agency objectives are met, as well as interagency, multi-agency, and international obligations. Analyzes relevant aspects of ORA's scientific program activities to ensure the elimination of duplication across the Agency and to promote effective resource utilization within ORS and/or with related programs performed in ORA, other Federal, State, local and international agencies.

Coordinates special projects relating to OMPTSLO/ORS analytical capacity and capability that cut across organizational and functional lines and insures that the AD-OMPTSLO, Director ORS and other ORA senior leadership is fully informed of the progress of such projects and that the views and policies are incorporated into the final product. Participates in the development of policies affecting the structure, personnel, and operations of MPTS laboratories. Provides executive leadership and direction in the further development and implementation of the ORS/ORA Science Strategic Plan.

Develops mechanisms to evaluate the effectiveness and efficiency of laboratory programs (including laboratory information, data handling, analytical methodology, equipment, facilities, and communications systems) and for determining if laboratory policies, procedures, and practices are meeting overall program objectives.

Reviews and analyzes policy documents forwarded to the AD-OMPTSLO affecting laboratory operations. Makes recommendations to the AD-OMPTSLO for action on such documents and performs other completed staff work.

Evaluates the Center's and laboratories' overall scientific efforts and activities and, as

necessary, develops, establishes or recommends scientific policy to the AD-OMPTSLO, the ORS Director and the Office of the ACRA.

Participates as needed with the AD-OMPTSLO, the ORS Director, senior officials and others in testifying before Congress on ORA programs and science activities. As Senior Scientific Advisor of information on OMPTSLO Science activities, provides authoritative advice, guidance, assistance, interpretations and recommendations to key agency officials, program directors, scientific and professional personnel, departmental representatives, intra/inter-governmental counterparts and others on scientific problems related to FDA/ORA guidance. Furnishes expert advice and comments on scientific matters related to existing and proposed policies, programs, regulations, proposed legislation and legislative strategy.

The incumbent is a proven leader, applying expertise and experience in building and directing complex scientific programs, including laboratory networks and demonstrated credibility with scientific peers through publications in peer review journals, presentations at scientific meetings, or other recognitions. Utilizes ability to collaborate with partners both internal and external on highly visible programs, including communicating on a peer-to-peer level with the Centers, and with FDA stakeholders.

Shows a clear understanding through the demonstration of the management of scientific personnel and financial resources. Knowledge and experience in strategic planning to develop new and/or modify existing programs. Demonstrates the ability to develop, establish, and implement scientific policy within laboratories and to outside entities.

On a continuing basis, meets and collaborates with scientists to maintain expertise related to ORS/ORA science with the goal of assuring all ORA activities are of the highest scientific caliber.

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 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.

Key requirements will include:

Candidates must possess the required individual occupational requirements to qualify for the Biological Sciences series, 0401; Microbiology Series, 0403; or Chemistry Series, 1320. Please use the following link to review the required qualifications: 401, 403, 1320.

Professional Experience/Desirable Qualifications:

- Recognized scientific authority in specialized programs associated with Medical Products, Tobacco and/or Specialty Laboratory projects and their components.
- Able to travel up to 25% to various FDA sites across the US. Initial travel may be greater, as onboarding requires familiarization with headquarters and laboratory facilities.
- Regulatory laboratory experience subject to ISO/IEC 17025 standards.
- Exceptional analytical skills, able to interpret and apply scientific instructions, policies, procedures and guidelines.
- Proven professional experience and stature in their area of expertise, commensurate with the duties of the position being filled.
- Demonstrated ability to approach assigned duties in a highly organized, detailed and accurate manner.
- Ability to manage multiple priorities and work in a flexible, dynamic and fast-paced environment.
- Excellent written and oral communication and influence skills, with the ability to inspire confidence and work successfully with diverse audiences.

- Demonstrated strength with organizational management, leadership and team-building.
- Creativity in problem identification and resolution and a relentless drive to accomplish company goals and objectives. A can-do attitude is a must.

Desirable Qualification/Experience:
Advanced degree in one of the following: biological sciences, chemistry, physical sciences, or related scientific fields that provide knowledge directly related to OMPTSLO responsibilities and experience as stated above.

Conditions of Employment:

Security Clearance:
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.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

Ethics Requirements:
This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

How to Apply: Applicants must submit a current résumé, a current SF-50 redacted for complete SS# and birth year (for federal employees only), proof of degree or transcripts (with foreign credentials evaluation if applicable), and a brief (one-page or less) statement explaining your interest and qualifications for this position to the ORA Executive Recruitment Team at: ORAExecutiveRecruitment@fda.hhs.gov by September 16.

For questions please contact Kathleen Davis at Kathleen.Davis1@fda.hhs.gov.

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