TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of the Director (OD)

Position: Associate Director for Science

Series: 0401/0403

Location(s): Silver Spring, MD

Travel Requirements: 10%

Application Period: July 17, 2020 to August 16, 2020

Salary: Starting at $197,241

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.

The mission of the Center for Biologics Evaluation and Research (CBER) is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

The conduct of applied scientific research on biologic products addressing key issues related to public health is an integral part of the mission of the Center for Biologics Evaluation and Research (CBER). The Associate Director for Science (ADS) is a key member of CBER's Senior Leadership Team and is responsible for high level strategy, promotion and coordination of all scientific research activities conducted by the Center and for assuring their high quality, focus and scientific, and public health outcomes. The ADS will lead the development of an overall strategy to address emerging scientific issues that affect CBER-regulated products and will also support the development and implementation of a research agenda that includes prioritization of research questions including those to be addressed in a collaborative manner with external stakeholders. The ADS also supports the scientific enterprise through guiding, developing and maintaining needed infrastructure and human resources.

Position Summary:

Within the framework of established policy and delegation of authority, the ADS makes management decisions pertaining to changes in course of approach, degree of program emphasis, allocation of resources, intramural and extramural cooperative ventures, and similar matters. The ADS develops and recommends policies for the execution of the scientific programs, determines their ongoing effectiveness, and recommends or develops new or revised scientific programs related to protecting and enhancing the public health with respect to the blood supply, vaccines, and biological therapeutics. In collaboration with senior officials, the ADS participates in the design and implementation of overall Center management policies including program planning, budget formulation, and resource allocation.

The ADS serves as the Center Director's principal advisor on all scientific program matters, including policies, practices and priorities:

- Represents and may act for the Center Director at high levels of CBER, FDA, HHS and throughout the US government in relevant scientific matters and to achieve program and national goals, including interaction with executives and legislative branches as well as the public and news media;
- Interacts extensively with Advisory Committees, other Agencies and a broad array of stakeholders to seek input, inform stakeholders about CBER plans and activities, achieve Center goals and leverage resources and knowledge;
- Advises the Center Director regarding the analysis of issues and problems confronting the Center scientific program, continually assessing the need for changes in priorities, policies and/or procedures necessary to improve the efficiency and responsiveness of the science program relative to other FDA and all other stakeholders;

- Initiates, coordinates, and/or responds to request for intra/inter-Center and Agency cooperation on scientific matters; and
- Stablishes and promotes a climate of collaboration with the scientific community and scientific organizations/institutions.

Supervisory responsibilities:

- Organizational Management: Manages a Staff.
- Program Management: Runs a multi-disciplinary program in the Center. May run two or more smaller, multi-disciplinary programs in the Center. Identifies specific activities needed to achieve desired outcomes. Organizational staffing patterns are primarily homogeneous, but may also have staff in various scientific, professional, technical, or administrative occupational series.
- Resource Management: Monitors and reports on resources needed to run an Office or a multi-disciplinary program in the Center.
- Personnel Performance Management: Counsels and rates immediate subordinates.
- Human Capital Management: Identifies employee competencies necessary to meet organizational capabilities goals.

Duties/Responsibilities:

The ADS is responsible for discussing key segments of planning and programming documents with Division, Office and Center officials and provides technical guidance, including the identification of deficiencies and recommendations on alternative approaches, in the development of the substantive content of the Center's short/long range plans and programming documents for the science program. The ADS is responsible for the review of Center scientific research programs and provides leadership and support to Offices and Divisions directors, laboratory/section chiefs and staffing in the planning, conducting, and coordinating of specific projects undertaken in the scientific research programs. The ADS coordinates research programs so that the scientific capabilities of the staff members in such diverse fields as microbiology, biochemistry, physiology, medicine, biophysics, population sciences and the engineering sciences, plus available research facilities, are effectively utilized. In addition, the ADS coordinates with other Centers throughout FDA that may impact upon or contribute to Center programs.

The ADS works closely with program leaders throughout CBER and FDA and performs or directs the routine and, where needed, targeted objective review of the scientific research program and project proposals to help assure the quality, mission relevance and effectiveness of

research plans. Identifies needs and opportunities for new programs or program changes based on changes in science and technology. Promotes and supports the scientific development and capacity of CBER scientists, including through appropriate peer review and career development activities. Helps assure that available resources are efficiently and effectively utilized in advancing the Center's mission. Assures full compliance with relevant laws, regulations and policies fosters collaboration with CBER including across organizational units, as well as within FDA, HHS and with outside stakeholders while helping assure the integrity and objectivity of our scientific processes and mission.

In addition, the ADS is directly responsible for the following:

- Administering programs for the interaction of the Center with outside organizations and for the transfer of technology to such organizations.
- Planning and coordinating the scientific training of the staff scientists to advance their capabilities in disciplines related to their specialties.
- Utilizing effective management techniques, practices, and principles to ensure that budgetary appropriations are expended productively, that personnel relations are conducive to the most effective productivity, and that scientists are stimulated to develop imaginative approaches to problems.
- Ensuring the quality of scientific standards utilized in the evaluation of biological products throughout CBER and coordinating standing and ad hoc Center committees on scientific and technical issues.
- Supervising all staff of the Associate Director for Science, including temporary consultants.

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.

Professional Experience/Desirable Qualifications:

The professional experience would include:

- Have primary responsibility for managing a scientific research program.
- Developing short and long term programmatic goals.
- Communicating scientific concepts to a lay audience.
- Supervisory experience is highly desirable.

Desirable Education:

Candidates would ideally have a master's degree, doctoral degree, or both in Biology or Microbiology.

Conditions of Employment:

Security Clearance:

Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. All information concerning qualifications is subject to investigation.

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: Submit resume or curriculum vitae with cover letter by August 16, 2020 to: CBERHumanCapital@fda.hhs.gov. Please reference Job Information: **OD-20-05**.

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