TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Commissioner (OC)
Office of Policy, Legislation and International Affair (OPLIA)
Office of Global Policy and Strategy (OGPS)
Office of Global Operations (OGO)

Position: Director, India Office
Series: 0685
Location: India
Travel Requirements: 25%, Travel Required
Application Period: March 03, 2021 – March 17, 2021
Salary: Starting at $163,962 (Cures Band F)
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 a term 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 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 Office of Global Policy and Strategy (OGPS) is to protect and promote the public health of Americans by effectively advancing FDA's public health mission globally. OGPS performs foreign inspections, and provides executive oversight, strategic leadership, and policy direction on FDA's global engagements including information sharing, international standards development, trade relations, and collaboration activities with partner regulatory authorities or multilateral institutions. Within OGPS, the Office of Global Operations (OGO) oversees the FDA's foreign offices, including staff in China, Europe, India, and Latin America. As evidenced in previous OIG, GAO, and media reports, OGPS has historically had difficulty recruiting and retaining candidates with appropriate skill sets, especially in the foreign offices.

OGPS is looking for individuals who not only have a thorough understanding of FDA's regulatory system, processes, and procedures but also a comprehensive understanding of how partner regulatory agencies or multilateral institutions regulate medical products.

Position Summary:

The Director of the India Office serves as the in-country agency focal point for international programs and interactions with foreign counterpart regulatory agencies, international organizations, foreign embassies and officials, the Department of Health and Human Services, and other USG components when country-specific issues are involved. The position requires access to national and sensitive information to support FDA's global mission.

Supervisory Responsibilities:

Manages a multi-disciplinary scientific and professional staff engaged in improving understanding of regulatory science, the essential components of well-functioning regulatory systems for FDA-regulated commodities, FDA requirements, horizon scanning, and developing and implementing regulatory policies and standards relevant to India. Provides leadership and management oversight to the India Office supervisors and subordinate support staff (25 direct hires and locally employed staff).

Duties/Responsibilities:

- Serves as an agency technical expert in working with senior, policy-level officials and technical specialist at other U.S. regulatory agencies, such as the U.S. Department of Agriculture, and others; which work in areas that impact FDA.
- Works closely with other U.S. agencies including the department of State, the U.S. Trade Representative toward the conception, development and implementation of agreements with foreign countries.
- Represents FDA senior leadership at meetings with international regulatory authorities or other governmental officials, foreign manufacturers, professionals, and collaborating associations involved with regulating, reviewing, evaluating, or developing FDA regulated products.
- Participating fully with the Associate Commissioner for Global Policy and Strategy and the Director of OGO, directs the implementation of new FDA policies, scientific and regulatory programs and activities that impact the mission of the office.
- Stays abreast of new developments in the area of responsibility within the host country or region; monitors and tracks new legislation, guidelines or policy initiatives; procures copies of supplementary legislation, new documents and other materials, and prepares appropriate reports to inform decision making at FDA headquarters.

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:

- Strong leadership and skill in leading/directing large organizations
- In-depth knowledge of the Agency's policies, and scientific and regulatory programs as they relate to medical products
- Strong background in science

- Talent for building partnerships and coalitions with stakeholders in public and private arenas

Basic Requirement:

Application must show experience in providing scientific leadership in formulating, developing, implementing and evaluating public health programs and scientific studies/surveys designed to improve public health programs.

Conditions of Employment:

This position is temporary and does not provide permanent placement upon completion or termination of the overseas assignment.

Selectees for temporary/term assignments will remain stateside until all required clearances and trainings are completed before being deployed to an overseas location.

Temporary/term appointments may begin stateside upon completion of security, medical and applicable trainings.

A Statement of Understanding is required to be signed by the selected candidate indicating they understand the terms and conditions of this temporary appointment.

NOTE: Current permanent civilian FDA employees selected for temporary overseas assignments will be given a return assignment to their permanent position, title, series and grade (or a comparable one within the commuting distance, i.e., 50-mile radius), once the appointment is completed. All other candidates, including current permanent Federal civilian employees, DO NOT have return rights to a position within FDA. "This position will be located New Delhi India. The temporary assignments not-to-exceed 2 years, but may be extended up to a total of 6 years. Eligible FDA employees will have statutory return rights to their permanent FDA position series and grade once the foreign assignment is completed.

PHS Commissioned Corps Officers interested in performing the duties of this position within the Commissioned Corps may apply to this announcement. Candidates will be referred to (CC) personnel and not as candidates for conversion to a permanent career or career-conditional appointment.

Displaced employees: If you are a former Federal employee who was displaced due to a Reduction-in-Force (RIF) or surplused by some other means, please submit a copy of the separation letter or RIF notice from your agency. To be selected under CTAP, you must still be found well-qualified for this position. *Learn more on the USAJOBS Career Transition Assistance Site.*

Security clearance and background checks:

This position requires a **Top Secret** security clearance for India; the incumbent has access to sensitive, proprietary, or financial information. 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 reinvestigation or supplemental investigation may be required at a later time. Applicants are also advised that all information concerning qualifications is subject to investigation. False representation may be grounds for non-consideration, non-selection and/or appropriate disciplinary action.

Ethics Requirements: Ethics pre-clearance is required.

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: Please submit resume or curriculum vita and cover letter to: Jessica.Lacey@fda.hhs.gov . A complete application package must be received by 11:59 PM (EST) on the closing date of March 17, 2021 to receive consideration. All applicants are required to reference source code: 21-001T21OCOGPS in the subject line and submit the following supporting document types (s):

- Resume or curriculum vitae
- Cover Letter

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

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