VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)

Food and Drug Administration (FDA), Office of Medical Products and Tobacco (OMPT)

Office of the Center Director (OCD)

Controlled Substances (CS)

Title 42 U.S.C. 209(f) Special Consultants

Position: Associate Director, Office of Controlled Substances (CS)

Series: This is an interdisciplinary, scientific position that may be filled in the biological sciences or health sciences

Location: Silver Spring, MD (White Oak Campus)

Salary Range: Salary is commensurate with education and experience.

Area of Consideration: Applications will be accepted from all qualified applicants.

Special Notes: This position will be filled as a Title 42 209 (f) appointment. This is an Excepted Service position under Title 42. This appointment does not confer any entitlement to a position in the competitive service and no entitlement to Merit Systems Protection Board (MSPB) appeal rights.

Conditions of Employment:

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) 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 http://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/default.htm.

Security and Background 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 at a later time. 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.

Organization:

This position is in the Department of Health and Human Services (HHS), Center for Drug Evaluation and Research (CDER), Immediate Office of the CDER Director (IO). The Center for Drug Evaluation and Research (CDER) is responsible for regulating prescription drugs, including generic drugs and over-the-counter drugs. The mission of CDER is to ensure that safe and effective drugs are available to the American people, and to ensure the public health mission is supported through scientific assessment of drugs for abuse and dependence potential and scientifically-based policy recommendations.

Duties/Responsibilities:

- Oversees all CDER activities related to both domestic and international drug scheduling and drug control, drug abuse liability assessment, and drug abuse and addiction. In this role he/she makes recommendations to CDER/FDA leadership regarding scheduling of licit and illicit drugs.

- Leads and supervises the Controlled Substance Staff (CSS), which includes a staff of scientists, physicians, and program managers that performs scientific and administrative functions under the Controlled Substances Act (CSA) related to drug scheduling recommendations by the DHHS to the Drug Enforcement Administration (DEA). In this capacity, the incumbent will work with the Director of the CSS, who will serve as the manager for the CSS. This staff, under his/her leadership, is the technical authority on all scientific decisions and judgments in connection with the abuse potential on central nervous system (CNS) active (psychotropic) drugs for CDER and FDA. In this role he/she is responsible for developing and maintaining the necessary skilled scientific staff within CDER to carry out this function.

- Serves as the FDA and CDER liaison for collaborations with other government agencies including the Drug Enforcement Agency (DEA), Office of National Drug Control Policy (ONDCP), the Substance Abuse and Mental Health Services Administration (SAMSHA), the National Institute of Drug Abuse (NIDA), the Centers for Disease Control and Prevention (CDC), and the Department of State regarding matters of drug scheduling and the identification of new trends in and risks related to abuse and dependence.

- Provides expertise on the Controlled Substances Act (CSA) as it relates to the work of the FDA, including drug scheduling based on scientific and regulatory assessments, both to other parts of CDER/FDA as well as to HHS.

- Develops policies and programs involving complex and high priority scientific matters affecting the regulation of controlled substances. Directs, drafts, and reviews documents on policy proposals and decisions on these products.

- In the role of developing policies and programs in this area, is aware of, and continuously appraises Center-wide ongoing drug product policies and in the review and analysis of program reports, proposals, memoranda, and other materials that affect the Center's operations and activities related to controlled substances. Identifies problems or issues related to the Center approaches to controlled substances, such as opioids, that need additional attention because of nationwide public concern and Agency interest.

- From an overall perspective with regard to CDER management of policies and approaches related to controlled substances, participates in and contributes to top level Center, Agency, or Department discussions, meetings, and conferences on broad policy matters and issues. Monitors, coordinates, and advises FDA/CDER on new or revised policy involving sensitive, controversial, and critical problems and complex issues related to major Center activities that may involve precedent-setting matters or concern problems or issues of particular concern to the FDA/CDER or the FDA Commissioner.

- Represents FDA at conferences and professional meetings in the U.S. and overseas, before the regulated industry, clinical investigators, and the medical/scientific community on the applicable regulations and policies. This is to communicate current policy developments at the Agency and to exchange information with stakeholders.

- Handles highly complex and controversial assignments of national scope and significance, ensuring that regulations and policies developed are consistent with the statutory requirements and existing policy and that adequate scientific and medical reviews have been completed.

- Provides scientific and policy leadership and guidance within CDER for activities related to interventions which may be used in FDA's public health response to the abuse of controlled substances. This includes work to prevent the abuse of these substances through effective risk management (e.g., scheduling of a drug) as well as identifying and implementing strategies to intervene in public health crisis related to the abuse of controlled substances (e.g., opioids). Provides leadership within CDER in designing and implementing policies and procedures to address the public health emergency regarding drug scheduling or the misuse or abuse of the drug.

Qualifications:

- Candidates must meet the minimum qualification requirements for the GS-15 or beyond in the civil service General Schedule and must have a strong scientific background and managerial experience.

In addition, for this specific position, applicants must meet the following:

Mandatory Professional/Technical Qualifications: -

Candidates must have a doctoral-level degree from an accredited institution of higher learning, including:

- Ph.D. or other research doctoral-degree widely recognized in U.S. academe as equivalent to a Ph. D.;
- 0405: Degree in an appropriate biological, medical, veterinary, or physical science, or in pharmacy that included at least 30 semester hours in chemistry and physiology and 12 semester hours in pharmacology.
- 1320: Degree in physical sciences, life sciences, or engineering that included 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics.
- Mastery knowledge of one or more professional fields (e.g. pharmacology, chemistry) and skill sufficient to identify and understand the most difficult, complex and broad agency regulations and provide executive leadership and guidance in an area that has major impact on public health.
- Possess a thorough knowledge of the mission and science policies and associated goals, structures, functions, and interrelationships in the Agency.
- A doctoral level knowledge of chemistry or related fields;
- Extensive knowledge of the development of human drugs, including statutory requirements, appropriate Agency guidance, and regulatory processes.
- Transcripts are a requirement to support the Ph.D.

Mandatory Managerial/Executive Qualifications:

Candidates must have the ability to bring about strategic change, both within and outside the organization, to meet organizational goals; the ability to lead people toward meeting the organization's vision, mission, and goals:

- Ability to meet customer expectations;
- Possesses the needed communications skills, both written and speaking, to interact effectively with both internal FDA groups, including the Commissioner, and external parties including the press, other HHS and US governmental Agencies, advocacy organizations, patient groups and other scientists.

Desirable Qualifications:

Candidates should have:

- Executive level administrative or managerial experience that demonstrates sound judgment, strong leadership abilities in a scientific or public health environment;
- Demonstrate leadership competence and abilities to:
    - develop complex and basic program goals, and assure that agency goals and priorities are considered in carrying out and completing OS's responsibilities;
    - direct and guide projects, including long-term and short-range planning;
    - establish objectives and priorities;
    - conduct periodic program assessments;
    - plan and direct the work of a large scientific review staff;
- Experience indicating the ability to communicate and effectively interact with high level government officials, the scientific/academic communities, medical or health related organizations, members of congress and top level representatives of counterpart Federal agencies, foreign government, officials, CEO level and senior representatives from regulated industry, and other stakeholders.

It is desirable that candidates have:

- Extensive knowledge in drug product development and manufacturing;
- Practical knowledge of the application of FDA laws and regulations;
- Training, professional development, and outside activities that provide evidence of initiative, resourcefulness and potential for effective job performance such as invitations, presentations and international activities;
- Receipt of honors, awards or other recognition for performance or contributions based on managerial excellence;
- Professional leadership activities

Application Procedures:

Candidates must submit a resume to: CDERExecutiveRecruiting@fda.hhs.gov

FDA is an equal opportunity employer