

Management Analyst

Description

Job Description – This position is located in the Department of Health and Human Services, Food and Drug Administration (FDA), Office of Dietary Supplement Programs (ODSP), Division of Research and Evaluation (DRE), Identity and Status Branch (ISB). ODSP has the primary responsibility to implement the Federal Food, Drug, and Cosmetic Act as amended by Dietary Supplement Health and Education Act (DSHEA) of 1994, which ensures the safety and truthful labeling of dietary supplements. ODSP also provides technical and policy input to support FDA legislative, compliance, enforcement, and public affairs initiatives relating to dietary supplement oversight. The ISB provides chemistry, microbiology, biology, and analytical chemistry expertise on dietary ingredients and supplements to the Center and develops guidelines and establishes expectations for the identity of dietary ingredients. **Special Notes:** This position will be filled under the Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS) appointment authority. This is an Excepted Service position. Candidates must submit a resume/curriculum vitae and copy of transcripts by close of business (July 15, 2022) to: CFSANExecutiveRecruitment@fda.hhs.gov.

Responsibilities – Duties/Responsibilities:•Serves as a national and international expert authority within CFSAN and across FDA, by providing authoritative and specialized biological, microbiological, or chemical expertise and analytical expertise in consulting on an array of regulatory issues and matters related to dietary supplements. •Directs the regulatory activities of the Branch, providing oversight for technical review for New Dietary Ingredient Notifications (NDINs), Ingredient Determination Memos (IDMs), and related evaluations pertinent to dietary supplements. •Manages and provides expert guidance on NDINs conducted by ISB staff including review of scientific information submitted by regulated industry as well as publicly available information or information generated by government facilities pertaining to the identity of dietary ingredients, how the substance is manufactured, and analytical chemistry information that allows determination of what substances are present in a dietary supplement. •Provides direction to highly trained and skilled multidisciplinary regulatory scientists. •Serves as spokesperson for the Center during conferences and at seminars, workshops and advisory committees on matters related to regulatory approaches to support the lawful use of ingredients in dietary supplements, including expert knowledge regarding the sourcing, manufacturing, and identity

Qualifications – Qualifications:1.To qualify for a SBRBPAS appointment, the individual must have a doctoral level degree in biomedicine or a biological related field, or a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field (to include chemistry or pharmacological sciences) and meet the OPM Qualification Standards for a General Schedule (GS) 15 level position in the applicable professional or

Hiring organization

FDA/CFSAN College Park, MD;
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Date posted

July 5, 2022

Valid through

15.07.2022

scientific series.2.In addition, the individual must be considered as an expert in the following field:Biomedical product assessment. An individual who is actively engaged in the development or assessment of biomedical products (including but not limited to experience in drugs, tobacco, biologics, devices and dietary supplement ingredients or food ingredients and whose work in this area is considered by recognized experts or peers in the field of biomedical product assessment to be outstanding. One or more of the following achievements must be present to demonstrate the individual has received such recognition: the individual a) has significant experience dealing with complex, precedent-setting evaluation, scientific policies or development issues (e.g., those associated with novel biomedical products, novel approaches to biomedical product – manufacturing (including but not limited to experience in drugs, tobacco, biologics, devices and dietary supplement ingredients or food ingredients), or use of novel evaluation approaches to dietary supplements; b) demonstrated cutting- edge expertise in a scientific or technical discipline critical to design, development, manufacturing, safety assessment, or technical aspects of effective oversight of biomedical products, including but not limited to dietary supplement ingredients/products or food ingredients; c) received invitations to speak at or chair major national or international meets and symposia; or d) meets other criteria demonstrating sufficient rigor or accomplishment in a relevant or closely related activity or field that is necessary to the accomplishment of the FDA Center/Office's mission. 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 organizational goals and customer expectations.•Ability to lead people towards meeting the organization's vision, mission, and goals.•Ability to build coalitions internally and with other Federal agencies, Federal, state, and local governments, nonprofit and private sector organizations, foreign governments, or international organizations to achieve common goals.Desirable Qualifications:Candidates should have:•Expert level experience that demonstrates sound judgment, strong leadership abilities in a scientific or public health environment;•Demonstrate leadership competence and abilities to:o develop complex and basic program goals, and assure that agency goals and priorities are considered in carrying out and completing ISB's responsibilities;o direct and guide projects, including long-term and short-range planning;o establish objectives and priorities;o conduct periodic program assessments;o plan and direct the work of a multidisciplinary scientific 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 or top level representatives of counterpart Federal agencies, foreign government, officials, CEO level and senior representatives from regulated industry, other research stakeholders, consumer organizations, and the general public.It is desirable that candidates have:•Extensive knowledge in dietary ingredients and dietary supplements;•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;•Serves on the editorial board of a recognized journal or in a leadership role of a scientific/professional society or regulatory body.

Contact – CFSAN-Outreach, CFSAN-Outreach@fda.hhs.gov

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Job Confirmation # – 206530714

Contacts

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