REIMBURSABLE DETAIL
Center for Tobacco Products
Office of Science

The Center for Tobacco Products, Office of Science is offering Detail opportunities for **Lead Interdisciplinary Scientist, GS-401/405/415-14**. Applicants at the GS-13 and GS-14 level are encouraged to apply. The Detail is available immediately for a period of 120 days. The incumbent acts as a Biologist, Pharmacologist, or Toxicologist working on toxicology research and review of tobacco products. The incumbent must be knowledgeable about tobacco product research and tobacco product application review, as well as understand the regulations and laws applicable to tobacco products. A temporary promotion may be considered.

Bargaining Unit Status: **Non-Bargaining Unit**

Position Office Location: FDA
Center for Tobacco Products
Office of Science
11785 Beltsville Drive
Calverton, MD

Opening Date: **August 26, 2019**
Closing Date: **August 30, 2019**

Area of Consideration: **FDA-Wide**

The Center for Tobacco Products (CTP), Office of Science (OS), Division of Nonclinical Science offers a fast-paced, dynamic environment and an opportunity to work with dedicated, energetic people who really want to make a difference and improve public health. The position is ideal for someone who wants to have a critical role in the organization and would enjoy the challenge of handling a variety of assignments related to the regulation of tobacco products.

Duties include:
The selected employee will serve as a Lead Biologist, Pharmacologist or Toxicologist in a Toxicology Branch that supports CTP's scientific review programs and activities, as they pertain to tobacco products and tobacco product regulation to support implementing the Family Smoking Prevention and Tobacco Control Act. Duties may include:

- Serves as a Team Lead who the Center and Agency recognizes as an expert and the authority regarding the biological, pharmacological, and toxicological impacts of tobacco products to address the risk and adverse health effects. Because of unique qualifications and experience, the incumbent applies extraordinary technical expertise to unique, critical and scientifically complex situations and develops new approaches to problems that are difficult.

- Provides authoritative and professional expertise in the biological, pharmacological, and toxicological impacts of tobacco products and their ingredients and constituents. Provides consultation and advice to the OS and CTP leadership in areas of tobacco products as related to toxicology.

- Reviews documents submitted for regulatory action; provides secondary review of documents prepared by other OS scientists.

- Demonstrates technical leadership by: (1) interpreting complex biological, pharmacological, and toxicological aspects of reports/submissions for tobacco products; (2) reviewing study protocols and offering recommendations related to study design; (3) interpreting scientific data and if needed, performing additional analysis of data submitted; (4) preparing a comprehensive synopsis of reviews of reports/applications with recommendations for revision, acceptance or rejection, and providing specific supporting reasons for the reviewer's recommended disposition and any technical deficiencies requiring action by the sponsor; (5) implementation of policies and recommendations.

- Provides advanced expertise by keeping abreast of new findings through review of scientific literature, participation in professional meetings and undertaking independent research. Proposes areas of study for regulatory toxicology research projects. Develops state-of-the-art toxicology projects to address gaps in scientific knowledge needed for effective regulation of tobacco products.

- Recognizes the need for, and initiation of, new and amended regulations, policies, guidances and procedures. Develops and recommends new and revised guidelines for regulated products. Provides scientific support in developing guidance and regulation.

- Provides expert advice and assistance to scientists and officials on a wide range of matters. Provides verbal and written conclusions to other federal agencies, industry, universities and state, local and foreign governments. The incumbent also compiles data to prepare presentations to support the Agency's recommendations on scientific issues.

- Ensures that the organization's strategic plan, mission, vision, and values are communicated to the team and integrated into the team's strategies, goals, objectives, work plans and work products and services.

- Articulates and communicates to the team the assignment, project, problem to be solved, actionable events, milestones, and/or program issues under review, and deadlines and time frames for completion.

- Leads the team in identifying, distributing and balancing workload and tasks among employees in accordance with established work flow, skill level and/or occupational specialization; making adjustments to accomplish the workload in accordance with established priorities to ensure timely accomplishment of assigned team tasks; and ensuring that each employee has an integral role in developing the final team product.

- Reports to the supervisor periodically on team and individual work accomplishments, problems, progress in mastering tasks and work processes, and individual and team training needs.

- Represents the team consensus and convey the team's findings and recommendations in meetings and dealings with other team leaders, program officials, the public, and other customers on issues related to or that have an impact on the team's objectives, work products, and/or tasks.

- Leads the team in assessing its strengths and weaknesses and provide leadership to the team in exploring alternatives and determining what improvements can be made (e.g., in work methods, processes and procedures).

- Performs other duties as assigned.

Desired Knowledge and Skills:

- Skill in applying the theories, principles and methods in the field of biology, pharmacology, toxicology in order to provide technical expertise and leadership to the team.

- Demonstrate the skill to identify problems, gather information, draw conclusions, recommend solutions, prepare papers and reports for publication, provide advice to other scientists, and negotiate acceptance and implementation of recommendations.

- Knowledge of CTP missions, programs and organizations structures sufficient to collaborate with other CTP staff on public health issues and problems.

- Excellent organizational skills.

- Skill in working collaboratively.

- Excellent oral and written communication skills.

Application Procedure:
Supervisory concurrence is required to accept a detail; it is NOT required to apply.
The detail opportunity is open to all qualified candidates at the GS-13 and GS-14 grade levels and USPHS Commissioned Corps Officers.

Interested applicants should submit a copy of their resume, most recent copy of SF-50, and statement of interest via email to:

Anne Gentilcore
Program Analyst
Office of Management, Center for Tobacco Products, FDA
Anne.gentilcore@fda.hhs.gov

If you are not currently in the 0401, 0405, 0415 series, please submit a copy of your transcripts with the requested documents.

Detail is reimbursable.
Travel Expenses will not be paid.

Candidates must express interest by August 30, 2019

This is not an official vacancy announcement under the Merit Promotion System