

REIMBURSABLE DETAIL/TEMPORARY PROMOTION OPPORTUNITY

CENTER FOR TOBACCO PRODUCTS

The Center for Tobacco Products is offering a Detail opportunity for a position as a **Regulatory Counsel, GS-301-14**. PHS Commissioned Corps officers are encouraged to apply. The Detail opportunity is available immediately for a period of 120 days.

Bargaining Unit Status: Non-Bargaining Unit Position

Office Location: FDA
Center for Tobacco Products
Office of Compliance and Enforcement
Division of Promotion, Advertising, and Labeling
10903 New Hampshire Ave.
Silver Spring, MD 20993

Opening Date: **07/15/2019**

Closing Date: **07/19/2019**

Area of Consideration: Open to all qualified Career/Career-Conditional
FDA employees

On June 22, 2009, the President signed into law the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Public Law 111-31). The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. To carry out this responsibility, FDA established the Center for Tobacco Products (CTP).

Major Duties:

This position serves as a Regulatory Counsel in the Office of Compliance and Enforcement (OCE) in the Division of Promotion, Advertising, and Labeling. Duties will include:

- Develop and critically review compliance policies and programs involving the most complex and highest priority matters affecting the compliance of the tobacco industry.
- Draft and critically review documents embodying the Federal Food, Drug, and Cosmetic Act and its implementing regulations, compliance policy and program proposals, and decisions on tobacco products.
- Prepare responses to correspondence from regulated industry on issues that are industry-wide in scope or have broad health implications that are precedent setting interpretations of FDA policy.

- Provide guidance and training to regulatory specialists and other compliance professionals within FDA on matters relating to his/her expertise.
- Participate in the decision-making process and in discussions and decisions concerning Division, Office, or Center plans and compliance programs and activities.
- Play a lead role in the preparation of analyses of the impact of proposed changes to FDA laws and regulations which affect the compliance functions, program segment(s), and activities of the Center.
- Lead project and programmatic efforts at the Division, Office, or Center level on an as-needed basis.
- Seek avenues to improve productivity and increase the quality of the work of the team.

Qualifications: Applicants with one year of specialized experience at the GS-13 grade level who meet the basic qualifications of the position may be eligible for temporary promotion.

Qualifying specialized experience includes:

- Experience designing, evaluating, and conducting comprehensive compliance procedures and evaluating evidence to achieve compliance relative to a wide range of commodities and/or manufacturing processes;
- Ability to advise others in the application of Agency rules, regulations, and procedures;
- Skill to identify problems, gathering information, drawing conclusions, recommending solutions, preparing reports, and negotiating acceptance and implementation of recommendations;
- Solid foundation in regulatory review work; and,
- Excellent oral and written communication skills.

Application Procedure:

Supervisory concurrence is required to accept a detail; it is NOT required to apply.

This detail opportunity is open to all qualified candidates at the GS-13 or GS-14 grade level and USPHS Commissioned Corps Officers.

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

Anne Gentilcore

Anne.gentilcore@fda.hhs.gov

CTP Office of Management

AND

Michele Quander
Michele.Quander@fda.hhs.gov
CTP Office of Management

For questions about this position, please contact Jesse Hardin 301-796-6830.

Travel/Relocation expenses will not be paid.

Applications/resumes must be submitted by 07/19/2019.

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