

**REIMBURSABLE DETAIL
CENTER FOR TOBACCO PRODUCTS**

The Center for Tobacco Products (CTP), Office of Compliance and Enforcement (OCE) is offering a Detail opportunity to Unclassified Duties (Equivalent to a Division Director). Applicants at the GS-15 level are encouraged to apply. PHS Commissioned Corps Officers may apply. The Detail is for a period of 120 days. **No Temporary Promotion.**

Bargaining Unit Status: Non-Bargaining Unit Position

Office/Duty Location: FDA
Center for Tobacco Products
Office of Compliance and Enforcement
Division of Product Compliance
10903 New Hampshire Avenue
Silver Spring, MD 20993

Opening Date: 3/14/2022

Closing Date: 3/18/2022

Area of Consideration: Open to all Career/Career Conditional CTP Employees Only

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. 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).

Duties include:

The incumbent serves as the Division Director, Division of Product Compliance in OCE.

The incumbent:

- Supervises, manages, and directs work in support of various compliance and enforcement activities.
- Manages compliance activities related to Premarket Tobacco Applications (PMTA), Modified Risk Tobacco Product Applications (MRTPA), and Investigational Tobacco Product (ITP) reviews and other appropriate regulatory submissions.
- Manages and coordinates activities related to all Postmarket Reporting and Surveillance for appropriate regulatory submissions.
- Manage and coordinates all Premarket application manufacturer and BIMO inspections request and reviews to support application review process.
- Oversees and coordinates Premarket Tobacco lab request, samples collection and ORA laboratory analysis to support all application reviews.
- Manages and coordinates the reviews of standalone pre-existing tobacco product submissions and issuance of pre-existing tobacco product status determination letters.
- Manages and coordinates predicate tobacco product reviews and determination of commercial

marketing status of such tobacco products used in Substantial Equivalence (SE) submissions and Request for Exemption from SE reviews (EX).

- Consults with OCE senior staff members and other Center personnel to develop recommendations for regulation and policy development, to address emerging issues related to new tobacco products.

Desired Knowledge and Skills:

- Knowledge of the various laws, regulations, and policies applicable to HHS and FDA governing or affecting the programs administered by CTP.
- Ability to analyze complex, legal, enforcement and other information and interpret the significance of this data under prevailing legal principles, as expressed in statutes, regulations, and case law.
- Solid foundation in regulatory review work.
- Excellent oral and written communication skills.
- Excellent organizational skills.

The incumbent will also be responsible for the below supervisory duties:

- Organizational Management
- Program Management
- Resource Management
- Personnel Performance Management

Application Procedure:

The Detail opportunity is open to all qualified candidates at the GS-15 grade level or Commissioned Corps Officers.

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

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

Michele Quander
Office of Management
Center for Tobacco Products
Michele.Quander@fda.hhs.gov

AND

Miranda Jones
Office of Management
Center for Tobacco Products
Miranda.Jones@fda.hhs.gov

For questions about this position, please contact Terry McDonald at Theresa.McDonald@fda.hhs.gov.

Travel Expenses will not be paid.

Applications/resumes must be submitted by Friday, March 18, 2022.

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