Background

On June 22, 2009, President Barack Obama signed into law the Family Smoking Prevention and Tobacco Control Act, giving the U.S. Food and Drug Administration (FDA) comprehensive authority to regulate the manufacturing, marketing, and sale of tobacco products. The new law represents the most sweeping action taken to date to reduce what remains the leading preventable cause of death in the United States.

Before enactment of the new law, tobacco products were largely exempt from regulation under the nation’s federal health and safety laws, including the Food, Drug, and Cosmetic Act. The FDA has regulated food, drugs and cosmetics for many decades, but not tobacco products, except in those rare circumstances when manufacturers made explicit health claims.

What the New Law Does

The new FDA law finds that tobacco products have been used to facilitate and finance criminal activities both domestically and internationally, and that illicit trade in tobacco products has been linked to organized crime and terrorist groups. The legislation defines “illicit trade” as “any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.”

To combat illicit trade in tobacco products, the law requires that:

- The labels, packaging and shipping containers of tobacco products sold in the United States “bear the statement ‘sale only allowed in the United States’”
- The FDA issue new regulations providing for detailed industry recordkeeping and close monitoring of the movement of tobacco products from the point of manufacture through distribution to retail outlets, and provide the U.S. government with inspection rights relating to such records
- Tobacco product manufacturers and distributors report suspected contraband trafficking of tobacco products
- The Comptroller General of the United States collect data on cross-border advertising and trade in tobacco products and submit a report to Congress within 18 months of the law’s enactment that includes recommendations on monitoring cross-border tobacco product trade and preventing and eliminating cross-border...
advertising of tobacco products

In addition, the law forbids several “prohibited acts,” including:

- Manufacturing, selling, holding or dispensing counterfeit tobacco products or counterfeit components of any tobacco product, including any counterfeit labels, tax stamps, or other markings
- Making, holding, selling or concealing any punch, die, plate, stone or other item designed to make counterfeit labels, markings or stamps in order to create counterfeit tobacco products
- Doing any other act that causes a tobacco product to become a counterfeit tobacco product
- Selling tobacco products in violation of a no-sale order (which would occur when the FDA has determined that a person has committed repeated violations of mandated marketing restrictions at a particular retail outlet)