



Tobacco Control
Legal Consortium



Fact Sheet

Submitting Comments on Tobacco Products to the FDA

Like other federal agencies, the Food and Drug Administration often invites comments from the public on proposed rules, notes and “guidance documents” that describe the agency’s thinking on regulatory issues. Although the thought of submitting comments to a federal agency may seem intimidating to the average person, the process is actually quite simple, due to an electronic submission system on a federal website called [Regulations.gov](http://www.Regulations.gov), which allows people to search, view and comment on rules quickly and efficiently online.

The U.S. government’s Federal Register publishes proposed rules and other documents on the [Regulations.gov](http://www.Regulations.gov) website. The site includes U.S. government regulations from nearly 300 federal agencies on a wide range of topics including many on tobacco product regulation (such as advertising, promotion, enforcement and compliance issues). Approximately 8,000 regulations are published each year and every day the public submits thousands of comments on proposed or final regulations.

Submitting comments to the Food and Drug Administration gives you an opportunity to share your knowledge or opinions about a proposed tobacco product rule or notice, as well as any data, research, legal or policy issues, recommendations, supporting materials or other information that may help the agency in the rulemaking process. The agency relies on this information in deciding whether to revise or adopt proposed rules and regulations. Members of the public and the health community, attorneys, the tobacco industry – all have views on tobacco regulation, and some proposed rules can attract thousands of comments.

Guidelines on submitting, searching and reviewing comments are on the [Regulations.gov](http://www.Regulations.gov) website. Comments can range from short and simple to long and detailed, and they can be submitted electronically or by mail. Comments are accepted within a defined time frame, known as an open comment period. Once you submit a comment, the FDA (or other federal agency) sends you a tracking number, and then processes and reviews your comment before posting it on [Regulations.gov](http://www.Regulations.gov) for public access.

By submitting comments to the FDA about proposed tobacco rules and regulations, you are participating in the rulemaking process, and may even have an impact on the way in which laws are implemented and administered. To learn more about the process of submitting comments on tobacco regulation to the FDA, visit www.Regulations.gov.

Last updated Nov. 2010