

## Get Involved

Tell us what you think! The Federal Register publishes notices of proposed rules and notices of availability of draft and final guidance documents. The public comment period begins once these notices are published and usually lasts 60 days. This is a chance for you to share your opinion!

## Stay Informed

Sign up for email notices and be among the first to know about pending rules and guidance documents. Give yourself time to prepare and submit your comments by signing up today:  
[www.fda.gov/TobaccoProducts/ResourcesforYou/ucm176164.htm](http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm176164.htm)

Published every weekday, the Federal Register is available on the Federal Register website ([www.federalregister.gov](http://www.federalregister.gov)) and on the Government Printing Office website ([www.gpo.gov](http://www.gpo.gov)).

## Questions?

CTP: 1-877-287-1373

FDA Dockets Management (Monday-Friday, 9 -4 EST):  
301-827-6860

For complaints and disputes, contact the Ombudsman:  
[Les.Weinstein@fda.hhs.gov](mailto:Les.Weinstein@fda.hhs.gov), 301-796-9239

For general Tobacco Industry Questions email:  
[tobaccoindustryquestions@fda.hhs.gov](mailto:tobaccoindustryquestions@fda.hhs.gov)

## Making Your Voice Heard

To establish or modify how tobacco products are regulated, the Center for Tobacco Products (CTP) at the Food and Drug Administration (FDA) requests public comment. Your participation is needed when we:

- ◆ publish proposed rules (also called regulations, which have the force and effect of law),
- ◆ issue guidance documents (statements of our current thinking on a topic), and
- ◆ conduct public meetings and hearings.

Together we can formulate the most effective policies and strategies to improve public health. Stay informed by signing up for email notices at [www.fda.gov/tobaccoproducts/resourcesforyou/ucm176164.htm](http://www.fda.gov/tobaccoproducts/resourcesforyou/ucm176164.htm)

## Tobacco Product Regulation

# Making Your Voice Heard

## Public Comment and the FDA Center for Tobacco Products



# Rulemaking and Guidance Documents Process

## About the Center for Tobacco Products (CTP)

Our mission is to protect Americans from tobacco-related death and disease. CTP is responsible for regulating the manufacture, distribution, and marketing of tobacco products. We strive to educate the public, especially young people, about the harms of regulated tobacco to prevent initiation and encourage cessation. Our vision is to make tobacco-related death and disease part of America's past.

Your voice matters! For the first time FDA has the authority to regulate tobacco products using a public health approach. Public participation in activities that lead to the development of regulations is invaluable. With your help, FDA formulates the most effective policies to improve the public health.

Announced and posted

Comment period begins

Comment period ends\*

Comments are reviewed

Final version is drafted

Published

Implemented

## What Makes an Effective and Useful Comment?

FDA decisions are based on science and law. Agency reviewers look for logic, good science, and other evidence in the comments they evaluate.

### ***Here are some suggestions for making sure that your comments have the greatest possible impact:***

- ◆ Provide a clear statement of whether you support or oppose the proposed rule or guidance document.
- ◆ Explain your suggested changes.
- ◆ Include data, research, and analysis that supports your position. *Include a copy of articles or other references.*
- ◆ Refer to the docket number listed in the Federal Register notice.

\* Please note that you can submit comments on guidance documents at any time, even after the guidance is finalized.

## How Do I Submit Comments?

### ***Electronic submissions***

- ◆ Go to [www.regulations.gov](http://www.regulations.gov)
- ◆ Search for rules or guidance documents by keyword, title, or docket #
- ◆ Click "Submit a Comment"
- ◆ Fill out the web form
  1. Enter your information
  2. Type your comment
  3. Attach data, research, articles or other reference tools
  4. Preview your comment
  5. Submit your comment
- ◆ Write down your Comment Tracking Number

### ***By Fax or Mail***

- ◆ See the notice in the Federal Register for the appropriate address and contact person.

When we receive a comment, it is recorded and placed in the docket—a public record of proposed regulations or other actions. The comment then becomes part of the public record. You can review the comments posted to a docket by going online to [www.regulations.gov](http://www.regulations.gov) or by going to FDA Dockets Management's reading room, located at *Room 1061, 5630 Fishers Lane, Rockville, MD*. Please note a submitted comment may not be immediately accessible.