



Telling the Public Health Story to the FDA: How the FDA Regulates Tobacco through the Rulemaking Process

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gave the U.S. Food and Drug Administration (FDA) unprecedented authority to regulate tobacco products.[1] The FDA exercises this authority through a process called rulemaking, which requires active public involvement in order for the best regulations to be adopted. Unfortunately, the voice of the public health community in this process can be drowned out by the often voluminous comments of the tobacco industry. This fact sheet is intended to give the public health community an overview of the rulemaking process and information on how to be an active participant. [2]

Q. What is the Family Smoking Prevention and Tobacco Control Act?

A. On June 22, 2009, President Barack Obama signed the Tobacco Control Act into law, giving the FDA comprehensive authority to regulate the manufacturing, marketing, and sale of tobacco products. The new law represents Congress' most sweeping action taken to date to combat the leading preventable cause of death in the United States. Before enactment of the law, tobacco products were largely exempt from regulation under the nation's federal health and safety laws, including the Food, Drug, and Cosmetic Act.

Q. What does the Tobacco Control Act do?

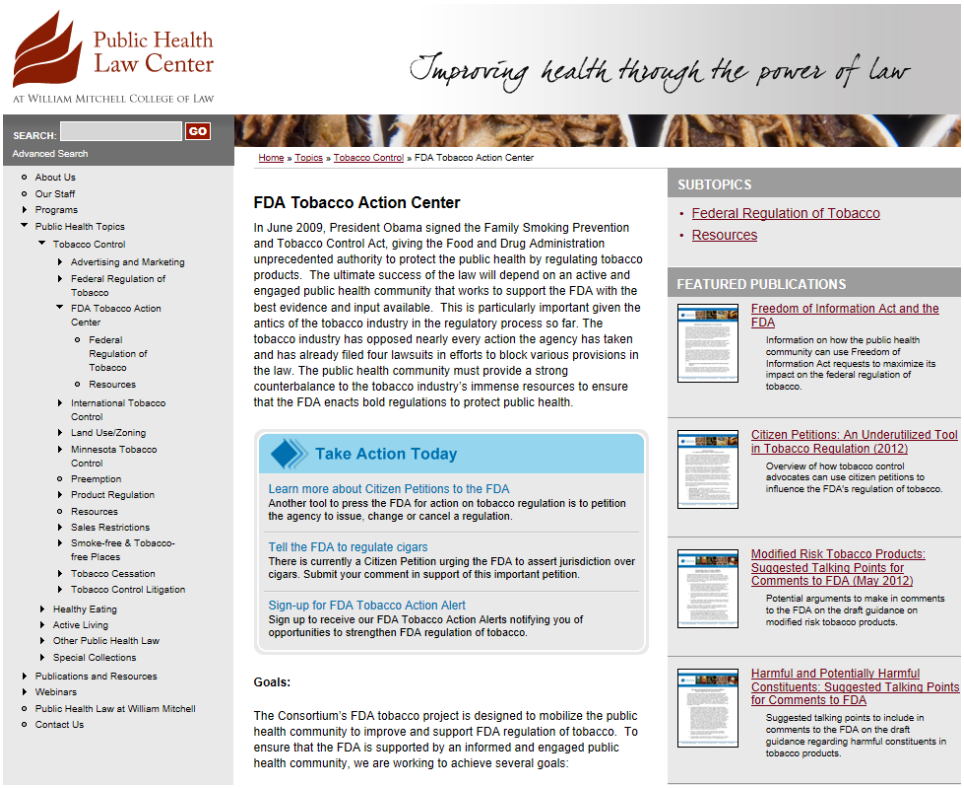
A. The law added a new Chapter IX to the Food, Drug, and Cosmetic Act, establishing and governing the regulation of tobacco products.[3] The law created a Center for Tobacco Products within the FDA[4] and directly mandated several tobacco control measures, including imposing restrictions on tobacco product marketing and advertising,[5] strengthening cigarette and smokeless tobacco warning labels,[6] and setting a nationwide standard for youth access to certain tobacco products.[7] The law also vested the FDA with jurisdiction to establish tobacco product standards,[8] review new tobacco products,[9] regulate the marketing of certain "modified risk tobacco products,"[10] and more. In carrying out these duties, the FDA must use a rulemaking process and follow the Administrative Procedures Act.[11]

Q. What is rulemaking?

A. In short, rulemaking is the process by which agencies create federal policy. While Congress is the only entity with the authority to enact federal statutes, an agency's properly issued rule, also called a regulation, has as much force of law as a statute passed by Congress. Agencies typically have greater subject matter expertise than Congress and are well situated to create nuanced policies. However, agency staff members are not democratically elected. As a result, there are several checks on the power of agencies to issue rules. One of these checks on agency authority is the requirement that the public must have the opportunity to comment on most proposed federal rules. See the Tobacco Control Legal Consortium's fact sheet *Laws, Policies and Regulations* for more information on this topic.

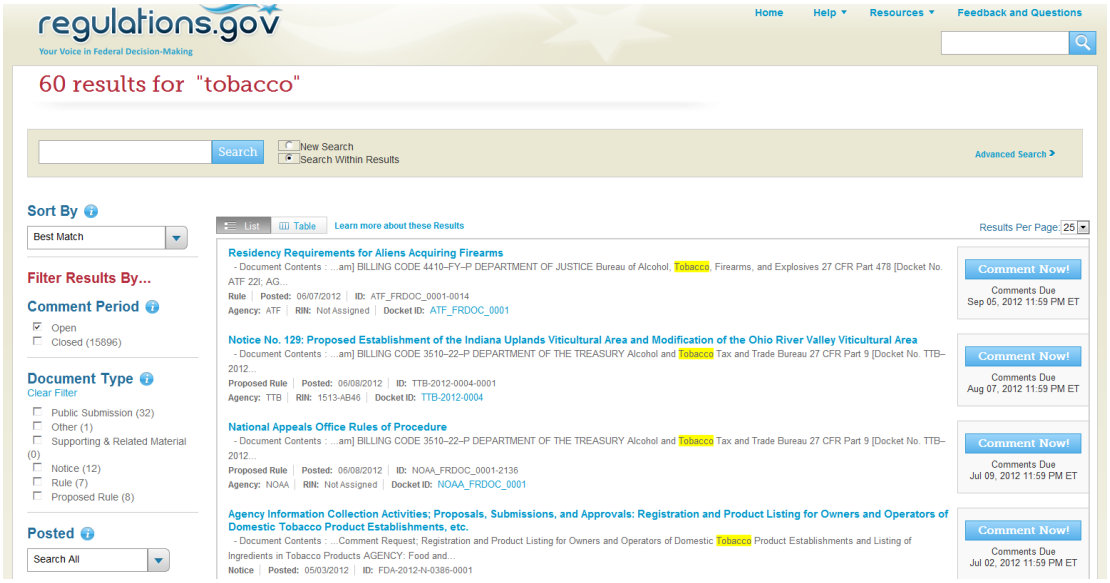
Q. How can I comment on proposed federal rules?

A. An agency may request comments at various stages of the rulemaking process. It may issue a request for information, an advanced notice of proposed rulemaking, or a notice of proposed rulemaking, depending on whether or not it has already prepared a proposed rule. The easiest way to find out about comment opportunities for FDA regulation of tobacco is to go to the Tobacco Control Legal Consortium's FDA Tobacco Action Center.[12] There you will find direct links to proposed regulations as well as fact sheets and other resources about federal regulation of tobacco.

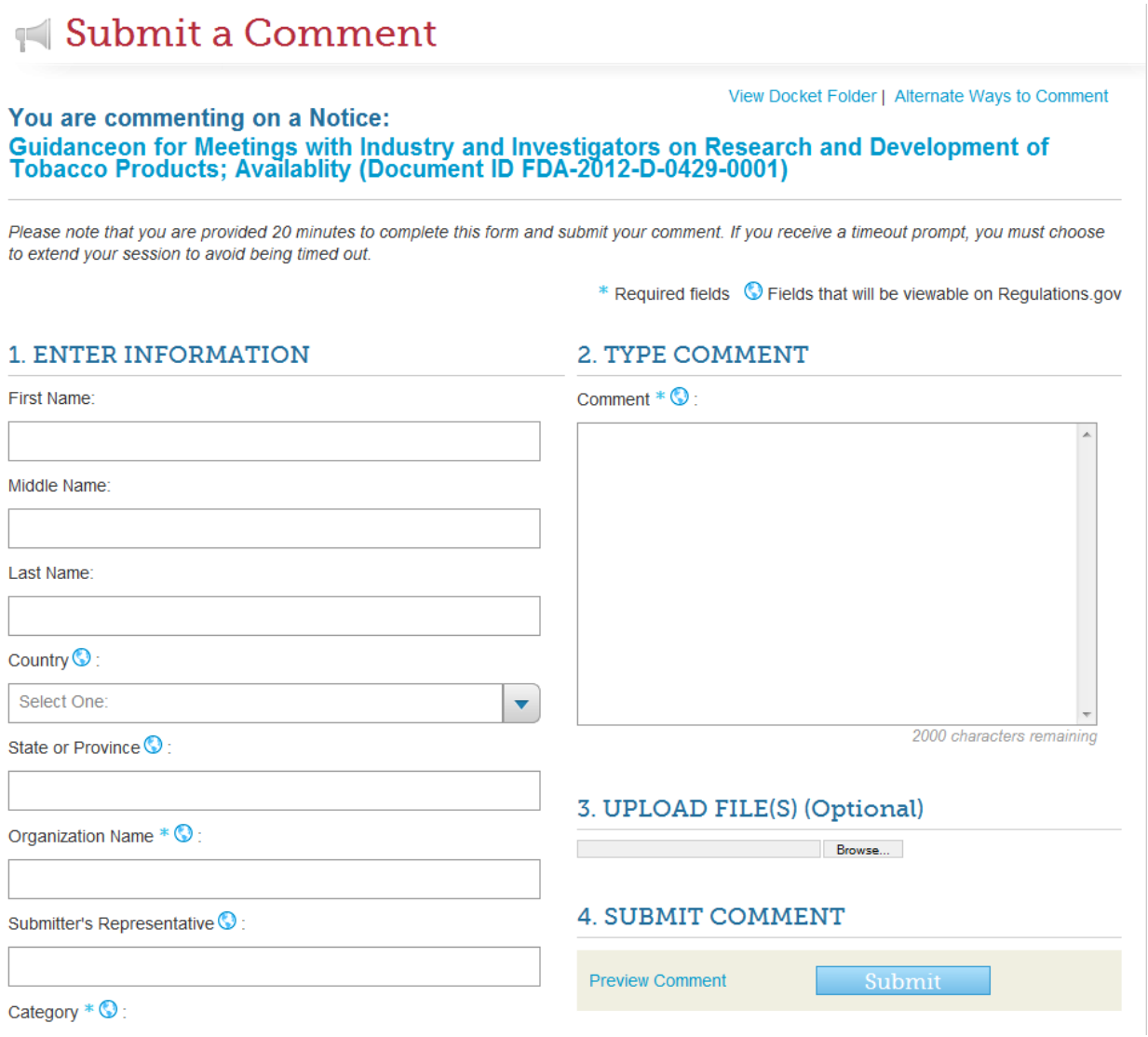


You can also learn about the topics in which the FDA is currently interested on the Center for Tobacco Products' website.[13]

You can search http://www.regulations.gov, the federal government's online source for regulatory information specific to tobacco control.[14] The screen shot below shows the results of a search for "tobacco" limited to the FDA.



Once you identify the proposed regulation or guidance on which you would like to comment, click the "Comment Now" button and you will see the following screen.



Comments can be submitted electronically by typing a short comment in the box or by uploading a document and clicking the "Submit" button.

Finally, all proposed and final rules are included in the Federal Register,[15] a daily publication that includes federal regulations. The notice of a proposed rule also contains a physical address to which comments can be mailed.

Q. How detailed should my comments be and what information should I include?

A. Comments need not be detailed, but should be sufficient to tell the agency information it may not know – whether it's something unique to your circumstances, an explanation of the importance of the issue in your community, preliminary data you have collected, interventions you have introduced in your community and their effects, a new scientific study, or simply your opinion. Anything that tells the public health story and counters the tobacco industry's self-

interested comments will help the FDA. The FDA can adopt tobacco product standards if it considers scientific evidence and determines that those standards would protect public health.[16] Your comments can help the agency meet this threshold.

Q. How will the agency use my comments concerning proposed rules?

A. The FDA will address all comments and reanalyze proposed rules in light of the comments submitted.[17] If the revised rule is substantially the same as the proposed rule, the rule is then made official. If the agency makes significant changes to the proposed rule after reviewing the comments, the revised rule is resubmitted for further comments before it becomes official.

Q. Could a final rule get challenged in court?

A. Rules are occasionally challenged in court. However, a court will overturn a rule only if one of the following things can be shown: the rule is arbitrary and capricious; it violates a constitutional right or privilege; it was issued in excess of statutory authority; or it was passed without the agency following proper procedures.[18] The first challenge in particular makes it critical that the agency has a strong record of comments supporting a public health position.

Q. Does commenting on proposed rules constitute lobbying?

A. The traditional rule has been that commenting on proposed rules does not constitute lobbying under the federal lobbying laws.[19] However, any person or organization considering commenting on federal rules should be aware of restrictions or requirements that may exist under other federal laws, state or local laws, or a contract with a funder. For example, a rider to the 2012 Consolidated Appropriations Act included language that could be interpreted as prohibiting organizations receiving certain federal funding from using those funds to comment on proposed rules. Specifically, the rider restricts the preparation of materials "designed to support or defeat any proposed or pending administrative action," including "any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing."[20] It is unclear how to interpret this language. For this reason, organizations should consult their attorneys and funders for guidance with respect to whether they are able to comment on proposed rules.

Glossary for Federal Regulatory Process

- **Docket**: A collection of documents related to a specific rulemaking or other administrative action. A docket folder may contain Federal Register documents, public comments, or petitions.[21]
- **Federal Register**: The official daily publication for rules, proposed rules, and notices of federal agencies and organizations, as well as executive orders and other presidential documents.[22]
- **Notice of Proposed Rulemaking**: A notice informing the public that an agency is proposing a new rule or a revision to an existing rule, providing the public with a period of time to comment on the proposed rule.[23]
- **Petition**: A request that an agency issue, amend, or repeal a rule.[24]

- **Promulgate**: To carry out the formal process of rulemaking by publishing the proposed regulation, inviting public comments, and approving or rejecting the proposal.[25]
- **Request for Information**: A tool used by an agency to help develop a proposed rule where the agency wants public input on whether a new rule or changes to an existing rule are needed, and comments on what course the agency should take should it decide to move forward.[26]
- **Rule**: A regulation issued by an agency that has the force of law.
- **Rulemaking**: The process by which an agency creates, amends, or repeals a rule or regulation.

Please note that the Tobacco Control Legal Consortium provides information and technical assistance on tobacco control issues, but does not provide legal representation or advice. If you have specific legal questions, we recommend that you consult with an attorney familiar with the laws of your jurisdiction.

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[1] 21 U.S.C. § 387a (West, Westlaw Next through P.L. 112-89 (excluding P.L. 112-55, 112-74, 112-78, and 112-81)); Family Smoking Prevention and Tobacco Control Act, Pub.L. No. 111-31, 123 Stat. 1776 (codified primarily at 21 U.S.C. §§ 387–387u. (2009)); 21 C.F.R. §§ 1140.30, 1140.32 (2010).

[2] *See also* Tobacco Control Legal Consortium, *Submitting Comments on Tobacco Products to the FDA* 1 (2010), *available at* http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-submittingcomments-fda-2010.pdf. The Tobacco Control Legal Consortium has produced several publications that describe the provisions of this law in greater detail. Please see our website for more information.

[3] 21 U.S.C. §§ 387–387u.

[4] *Id*. § 387a(e).

[5] Family Smoking Prevention and Tobacco Control Act § 102(a).

[6] *Id.* §§ 201, 204.

[7] *Id.* § 102(a).

[8] 21 U.S.C. § 387g.

[9] *Id*. § 387j.

[10] *Id*. § 387k.

[11] *Id*. § 387a(d).

[12] http://www.publichealthlawcenter.org/topics/tobacco-control/fda-tobacco-action-center

[13] http://www.fda.gov/TobaccoProducts/default.htm

[14] http://www.regulations.gov/#!searchResults;cp=O;dct=PR%252BFR;rpp=10;po=0;s=tobacco

[15] https://www.federalregister.gov/

[16] *Id*. § 387g(a)(3).

[17] 5 U.S.C. § 553(c) (2006).

[18] *Id*. § 706(2).

[19] 2 U.S.C. § 1602(8)(B)(x) (2006).

[20] Consolidated Appropriations Act, Pub. L. No 112-74, Tit. V, Sec. 503 , 125 Stat. 786, 1110 (2012).

[21] *Frequently Asked Questions,* REGULATIONS.GOV, http://www.regulations.gov/#!faqs (follow "What is a docket folder?"(last visited Feb. 21, 2012).

[22] FEDERAL REGISTER: THE DAILY JOURNAL OF THE UNITED STATES GOVERNMENT, https://www.federalregister.gov/ (last visited Feb. 21, 2012).

[23] U.S. Dep't of Labor, *Glossary of Rulemaking Terms*, http://www.dol.gov/regulations/glossary.htm (last visited Feb. 21, 2012).

[24] 5 U.S.C. § 553(e).

[25] BLACK'S LAW DICTIONARY 1334 (9th ed. 2009) (definition 3).

[26] U.S. Dep't of Labor, *supra* note 23.