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Making Your Voice Heard at FDA: How to Comment on Proposed Regulations and Submit Petitions

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E-Comments

You can [submit your comments](#) through the FDA Website on many of FDA's proposed regulations.

As a regulatory agency, FDA publishes rules that establish or modify the way it regulates foods, drugs, biologics, cosmetics, radiation-emitting electronic products, and medical devices--commodities close to the daily lives of all Americans. FDA rules have considerable impact on the nation's health, industries and economy. These rules are not created arbitrarily or in a vacuum. They are formed with the public's help.

By law, anyone can participate in the rule-making process by commenting in writing on rules FDA proposes. FDA routinely allows plenty of time for public input and carefully considers these comments when it draws up a final rule.

FDA gathers public comments mainly through two channels: proposed rules and petitions.

Proposed Rules

When FDA plans to issue a new regulation or revise an existing one, it places an announcement in the [Federal Register](#) on the day the public comment period begins. Published every weekday, the Federal Register is available at many public libraries and colleges, and on the FDA Website. [Issues open to public comment](#) often are reported by the news media and can also be found on FDA's Website.

In the Federal Register, the "notice of proposed rulemaking" describes the planned regulation and provides background on the issue. It also gives the address for submitting written comments and the name of the person to contact for more information.

Also noted is the "comment period," which specifies how long the agency will accept public comments. Usually, the file--or docket--stays open for comments at least 60 days, though some comment periods have been as short as 10 days or as long as nine months. Weekends and holidays are included in the comment period.

When submitting a comment by mail or in person, you do not need to follow any special style. If the comment is written legibly or typed on standard 8-1/2 inch by 11 inch paper, however, FDA can process the comment more effectively.

Comment Online

To comment electronically, log onto the "FDA Dockets Management" page at <http://www.fda.gov/ohrms/dockets/>. In the left-hand column under "Dockets" click on "Submit Electronic Comments", which will open the list of "Dockets Open for Comment". Locate the desired proposal by using the "Sort" or "Docket Search" capabilities. Click on the "Docket ID" link for additional information about the document and links with the appropriate Federal Register text and the "Docket Management Comment Form".

Follow carefully the screen instructions for entering your comment and attaching any electronic documents. You must enter the required information in each field marked by a red asterisk to successfully complete the form. If your comment is in the electronic attachment, write "see attached file" in the "General Comment" field. If you need additional help, return to the "Dockets Open for Comment" page and click on "Frequently Asked Questions."

Here are some other suggestions for making sure your comment has the greatest possible impact:

- Clearly indicate if you are for or against the proposed rule or some part of it and why. FDA regulatory decisions are based largely on law and science, and agency reviewers look for reasoning, logic, and good science in comments they evaluate.
- Refer to the docket number, listed in Federal Register notice.
- Include a copy of articles or other references that support your comments. (Electronic attachments will not be forwarded if the "Comment" box is left empty.)
- Only relevant material should be submitted. If an article or reference is in a foreign language, it must be accompanied by an English translation verified to be accurate. Translations should be accompanied by a copy of the original publication.
- To protect privacy when submitting medical information, delete names or other information that would identify patients.
- Comments must be postmarked, e-mailed or delivered in person by the last day of the comment period.

When FDA receives a comment, it is logged in, numbered, and placed in a file for that docket. It then becomes a public record and is available for anyone to examine in FDA's reading room (Room 1061, 5630 Fishers Lane, Rockville, Md.). Under the Freedom of Information Act (FOIA), visitors to the reading room can receive free copies of comments up to 50 pages if their request is for noncommercial use. After that, each page costs 10 cents. People also can send FDA an FOIA request and have copies of comments mailed to them.

Petitions

Another way to influence the way FDA does business is to petition the agency to issue, change or cancel a regulation, or to take other action. The agency receives about 200 petitions yearly.

Petitions require careful preparation by the submitter. FDA spends considerable time and staff resources processing petitions. Individuals sometimes submit petitions, but most come from regulated industry or consumer groups. For example, a drug company might request a change in labeling for one of its products; a food company might ask that its product be exempted from some provision of a regulation; or a consumer group might petition FDA to tighten regulation of a certain product.

Petitions submitted to FDA must contain:

- Action requested--What rule, order, or other administrative action does the petitioner

want FDA to issue, amend or revoke?

- Statement of grounds--The factual and legal grounds for the petition, including all supporting material, as well as information known to the petitioner that may be unfavorable to the petitioner's position.
- Environmental impact--This information is generally required if the petition requests approval of food or color additives, drugs, biological products, animal drugs, or certain medical devices, or for a food to be categorized as GRAS (generally recognized as safe). Procedures for preparing environmental impact statements can be found in [Title 21, Part 25 of the Code of Federal Regulations](#). If an environmental impact statement is not required, petitions should include a statement to that effect.
- The following official certification statement --"The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition."
- Identifying information-- The petition must be signed and include the petitioner's address and phone number.

In addition, some petitions may require information on:

- Economic impact--This information is required only if FDA requests it after review of the petition.

FDA currently does not accept e-mailed petitions. Petitions must be mailed or delivered to: Dockets Management Branch, Food and Drug Administration, Room 1061, 5630 Fishers Lane, Rockville, MD 20852.

Ultimately, FDA management decides whether to grant a petition. But first, agency staffers evaluate it, a process that may take several weeks to more than a year, depending on the issue's complexity. After FDA grants or denies the petition, the agency will notify the petitioner directly. If not satisfied, the petitioner can take the matter to court.

For more information on submitting petitions, and sample formats, consult Title 21 of the Code of Federal Regulations, [Sections 10.30](#), [10.33](#), and [10.35](#).

Besides accepting public comments and petitions, FDA also schedules public meetings and hearings to discuss and explain its proposals. These usually are held with industry representatives or consumer groups, but anyone interested may attend and, with advance notice, may comment on a proposal. Meetings often are held in the Washington, D.C., area, but sometimes are set in other areas across the country. Meetings for the public to present views are announced in the Federal Register.

Copies of [comments](#) on FDA issues are available on the FDA Website.

Questions about the comment, petition or hearing process should go to the FDA Dockets Management Branch, (301) 827-6860. Hours are 9 a.m. to 4 p.m., Eastern time, Monday through Friday.

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