



The FDA Docket

Frequently Asked Questions (FAQs)

Where can I sign up to receive alerts about dockets?

https://www.federalregister.gov/my/sign_up

How long are dockets normally open for comment?

The FDA Center sponsoring the docket determines the length of the comment period, and dockets are open for comment as long as deemed necessary. For FDA citizen petition dockets, this is usually 180 days. It may be more or less depending upon the type of docket.

What happens after I submit my comment?

Your comments are routed to the appropriate Center/Office/Program personnel. All comments are read and used in the decision making process.

Comments are not always individually responded to; instead they may be mentioned in a Federal Register (F.R.) Publication or petition response.

Can I comment on a docket multiple times?

You may submit as many comments as you like. However, equal consideration is given to each comment, so it does not help to submit multiple comments with the same suggestions.

Are public comments available in real time or are they only available after the docket closes?

FDA is required to screen all comments submitted to ensure language is appropriate, to ensure there is no confidential commercial information, etc. This process means comments can take time to be posted, however comments can be available before the comment period closes. However, many people comment the last day of a comment period, so that may be a reason many comments are not available until the comment period is concluded.

Will my comment carry more weight if I sign many petitions with different organizations on the topic?

It is helpful to know how many stakeholders share a perspective, however a long list of signatures on a comment does not necessarily add more weight to the suggestion, it is more important to include the rationale for your argument. FDA considers all comments submitted to a docket.

How do I delete/remove submitted comments?

Once a comment has been submitted to a docket it becomes a part of the official administrative record and cannot be deleted. However, if the comment has been posted for public view and the submitter requests to have his/her comment removed it can be restricted – not withdrawn – from public view.

To have your comment withdrawn from public view, submit a request to the Federal Dockets Management Staff.

How long does Dockets Management have to respond to my complaints/disputes?

Dockets Management generally does not respond to complaints/disputes.

If the complaint is regarding difficulties in submitting comments to a docket via regulations.gov, the submitter should contact regulations.gov for assistance.

If the comment is a citizen petition to the FDA requesting that the Commissioner take action on an issue, FDA usually has 150-180 days to provide the initial response.

If it is a Freedom of Information Act (FOIA) Request the agency generally has 20 days to respond.

Are there any resolutions to the comments submitted?

If the document is a petition instead of a collection of comments, the petition will be answered. If the comments address an ongoing issue they are used as resources to gauge the public's opinion and aid in the decision making process.

Where can I find this information for future reference?

www.FDA.gov/MinorityHealth

www.regulations.gov

<http://www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm>

Common abbreviations and synonyms for docket:

Federal Register (FR) Notice, docket, request for comment

What are some other ways I can make my voice heard at FDA?

Patient meetings <http://www.fda.gov/ForPatients/Calendar/default.htm>

Become a consumer or patient representative www.fda.gov/ForPatients/About/default.htm

Join an advisory panel www.fda.gov/AdvisoryCommittees/default.htm