

Providing Comments on CDER Level 2 Guidances

Per FDA's regulations at 21 CFR 10.115 on Good Guidance Practices Level 1 guidance documents include those that:

- Set forth initial interpretation of statutory or regulatory requirements
- Set forth changes in interpretation or policy that are or more than a minor nature
- Include complex scientific issues or
- Cover highly controversial issues.

Level 2 guidance documents are described as documents that set forth existing practices or minor changes in interpretation or policy. After the development of a Level 2 guidance, the Good Guidance Practices allow FDA to post the document and immediately implement the policies described in the guidance unless indicated otherwise.

Unlike Level 1 guidances where the availability of that guidance must be announced in the Federal Register, Level 2 guidances do not have this requirement. However, the public may comment on Level 2 guidances at any time. This document tells the public how to submit electronic comments to a Level 2 guidance to ensure that comments are for the correct guidance and routed to the proper office for consideration.

How to submit comments

When submitting electronic comments to a Level 2 guidance, please identify the guidance the comments are for by including the full title of the document in your comment. For example: "This comment is for the guidance titled "How to Provide Comments on CDER Level 2 Guidances"

Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.