The Right Way to Prepare and Submit a Comment

GENERAL COMMENT ADVICE

1) Follow the instructions below carefully – Comments received by FDA which do not comply with the agency's regulations for Comment submissions may be **REJECTED**,[1]

2) Comments which simply complain about FDA regulation, or which simply criticize the agency, are unlikely to be considered. Comments are a regulatory submission to a government agency – only serious submissions are considered (**BE CONSTRUCTIVE – DO NOT COMPLAIN!**),

3) While it is not required, FDA recommends that Commenters opposed to a Proposed Rule provide suggested improvements or potential alternatives to the Proposed Rule,[2]

4) If your Comment relies on data or information contained in any studies, reports, court cases, other laws or regulations, etc., you **must** attach a complete copy of these items to your Comment,

5) You can submit Comments with some information marked "Confidential", which will not be publicly published, such as your personal identifying information or business information, provided instructions for doing so are closely followed (instructions for Comments with confidential information are provided below),

6) Submit as early as possible; the deadline for Comments to this Proposed Rule is **11:59pm EST, October 15, 2024.** Comments are considered "submitted" on the date they are postmarked (unless they are delivered in person during regular business hours, in which case they will be considered "submitted" on the date delivered (for mailed Comments). Electronically submitted Comments are considered "submitted" on the date received.

[1] 21 CFR § 10.20(c)(6).
[2] 21 CFR § 10.40(b)(5); "Persons submitting comments critical of a proposed regulation are encouraged to include their preferred alternative wording."

YOUR COMMENT FORMAT

Highlighted sections below should be replaced with your information and content

[Prepare on your company letterhead, with name, address and phone number]

[*Date*]

Submitted Electronically via Regulations.gov; Docket FDA-2024-N-1111

[*OR- Based on the method used to submit this, choose the above or below bolded text]*

Submitted via USPS Priority Mail

Dockets Management Staff [HFA-305]
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville MD 20852

RE: Comment on Proposed Rule, Docket FDA-2024-N-1111

Dear U.S. Food and Drug Administration,

This submission is a **Comment** on Proposed Rule, *Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Certain Tobacco Products*, Docket Number **FDA-2024-N-1111**, timely submitted ahead of the October 15, 2024, 11:59pm EST deadline.

This Comment on the Proposed Rule is submitted pursuant to the Administrative Procedure Act, 5 U.S.C. § 553,[3] the U.S. Food and Drug Administration's Comment regulations,[5] and the instructions contained in the Proposed Rule ("*Instructions*").[4][6]

[Provide a brief introduction to yourself, and/or your company, and your company operations – this lets FDA know that you know the industry and that your Comment should be taken seriously]

[Type your comment; including stating your opposition clearly, identify specific flaws with the Proposed Rule, explain how the Proposed Rule will harm businesses and affect consumers, and give examples of problems the Proposed Rule will create rather than solve]

[Concluding remarks]

Respectfully submitted,

*[Signature - your Comment **must be signed**[7]]*

Encl.

*[List any enclosures/attachments, such as studies, reports, or data referenced in your Comment – remember, copies of these **must** be included]*

[3] 89 FR 66647 (August 16, 2024).
[4] 89 FR 66647, 66647 (August 16, 2024).
[5] 21 CFR § 10.20(b).
[6] 89 FR 66647, 66648 (August 16, 2024).
[7] 21 CFR § 10.20(b).

INCLUDE / DON'T INCLUDE TIPS

Include:

1) Professional writing, appropriate punctuation, and the required format for Comments to be considered by FDA,

2) Information about your employees, and the families who depend on your business,

3) Your specific industry knowledge, and how your expertise relates to your Comment,

4) Your personal experience and observations – remind FDA that its policies and rules impact real people and real businesses,

5) Data, estimates, and insights related to consumer habits (generally) and smoking cessation (particularly former smokers who rely on vape products),

6) Consumer survey responses and data from your operation, location, or region,

7) Your knowledge of illegal imports/smuggling and other illegitimate markets which others will migrate to in order to bypass the Proposed Rule, if enacted,

8) Reasonable alternatives to the Proposed Rule, such as identification of the sources of dangerous vape products entering the U.S., and focusing on those,

9) Examples of policy failures resulting from similar attempted bans (we can think of quite a few…).

Don't include:

1) Commentary about other issues unrelated to the Proposed Rule,

2) Heavy speculation, or estimates ("guestimates") without any supporting data or specialist knowledge,

3) Irrelevant or "scurrilous"[8] information, which could cause your comment to be rejected,

4) "Boilerplate language" (i.e., generalized statements, often clearly copied and pasted from other sources),

5) "Conclusory statements" (i.e., conclusions about the negative impacts of the Proposed Rule without any support, such as "The Proposed Rule will kill jobs.") Rely on data, known facts, or your own expertise,

6) Business information, disclosures, web addresses, or other content which could give FDA any impression that you or your business may violate the Food, Drug and Cosmetics Act.

[8] 21 CFR § 10.20(c)(5).

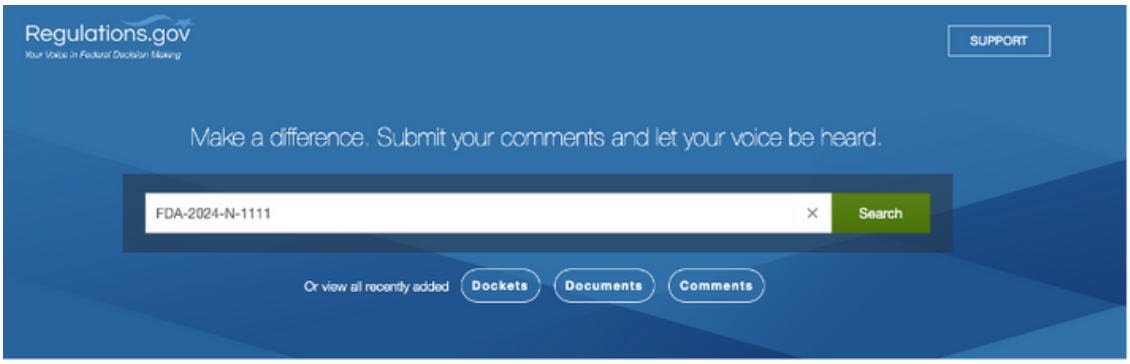
HOW TO SUBMIT YOUR COMMENT

Electronic Submission

NOTE: Comments submitted electronically **cannot be Confidential**! If you wish for any of your information, or any of the information contained within your Comment, to remain Confidential, you ***MUST*** submit your Comment in paper form by U.S. Mail (instructions further below).

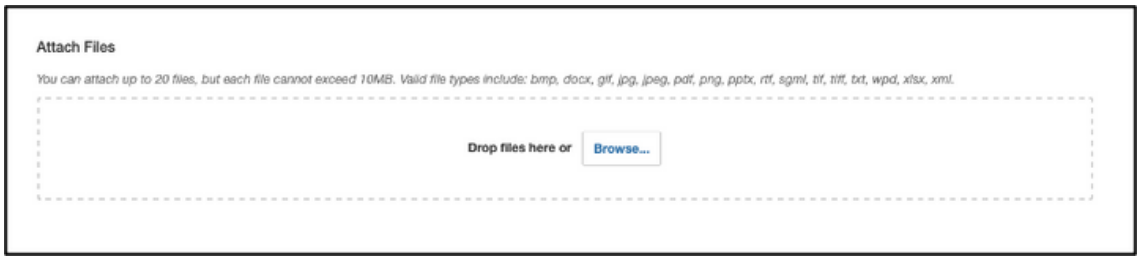
Comments may be submitted electronically at ***www.Regulations.gov*** by following the steps below.

First, locate the correct Docket Number for the Proposed Rule by searching ***FDA-2024-N-1111:***



Next, select the Proposed Rule, which can be identified by the "PR" in the top left corner:

Select the "Comment" tab (shown above), begin completing the required information and drop-down menu selections, and upload your Comment document(s) (in **PDF** format):



Once you have completed all required fields and verified that your Comment PDF document has been uploaded, you can submit by clicking the "Submit" tab.

Paper Submission by U.S. Mail

If you would prefer to submit your Comment on paper by U.S. Mail, this can be done by mailing you Comment to the FDA office in the document heading:

Dockets Management Staff [HFA-305]
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Once again, with mailed Comments,

1) Ensure you enclose a complete printed copy of all studies, reports, court cases, other laws or regulations, etc., which your Comment relies upon or references,

2) Remember that your Comment **must be signed**,

3) It is recommended that you send your Comment via USPS Priority Mail so that you can track your parcel and have delivery confirmation (as FDA **will not** confirm receipt of Comments).

Instructions for Confidential Submissions

Comments containing Confidential information **must be submitted in paper form by mail** per the instructions above, with the following **additional requirements:**

1) Enclose **two (2) copies** of your comment:

a. Copy one (1) will be your Comment in its entirety, with a clear heading at the top of the document reading "**THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION**" (*this is the version FDA will consider*),

b. In Copy two (2) of your Comment, you should carefully **redact/black out** all information you claim as confidential (*this is the version FDA will publish*).

If you do not wish for your name and contact information to be publicly published, provide your name and contact information in a Cover Letter, and indicate in the Cover Letter that you do not want your name and contact information publicly published. Be sure not to include your name and contact information in your actual Comment document if this is the case.

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Where you have questions about any of the above when preparing your Comment, please contact the Clark-Esposito Law Firm, P.C. at **(917) 546-6997**, or by email at contact@clarkespositolaw.com.

About Clark-Esposito Law Firm, P.C.

As always, for Proposed Rules which may ultimately impact our business network and clients, we will continue to closely monitor the development of this rule, any changes, and its Final Rule versions, should it become a Final Rule.

Why Clark-Esposito Law?

We are a New York and Connecticut-based regulatory compliance law firm dedicated to fighting the toughest government battles, allowing our clients to maintain their primary focus. Partnering with us means safeguarding your company, preserving business operations, and upholding your valuable reputation.

How to Get Started

At Clark-Esposito Law, we've streamlined the process of collaborating with us. Our commitment lies in thoroughly grasping your requirements and suggesting efficient solutions that can be swiftly implemented. Our client-centric communication approach guarantees efficiency, preventing unnecessary time or billable hours from piling up. Book your introductory call below.

The clock is ticking, and failing to engage in this process could have long-term consequences for your business and the industry. Do not wait for your products to be blocked at the border. We are here to help ensure that your business survives, and thrives, in this rapidly changing regulatory landscape. Contact us today!