



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0529]

Draft Concept Paper: Illicit Trade in Tobacco Products after Implementation of a Food and Drug Administration Product Standard; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft concept paper entitled "Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard." FDA seeks public comment on the draft concept paper regarding the potential for illicit trade markets to develop in response to a tobacco product standard. This draft concept paper is offered to stimulate dialogue around the subject of possible illicit trade in connection with tobacco product standards.

DATES: Although you can comment at any time, to ensure that the Agency considers your comment on this draft concept paper, submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged.

- 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>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-0529 for "Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard."

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this draft concept paper to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft concept paper may be sent. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the draft concept paper.

FOR FURTHER INFORMATION CONTACT: Christopher Griffiths, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft concept paper entitled "Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard." On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (Tobacco Control Act) was enacted. The Tobacco Control Act grants FDA authority to implement a wide variety of product standards impacting different characteristics of existing and future tobacco products. This draft concept paper describes aspects of the tobacco product market and consumer behavior that may be relevant to the development of illicit trade markets if FDA implements a tobacco product standard. FDA faces a complex task when assessing the potential for an illicit trade market to develop in response to a tobacco product standard. While it remains difficult to measure existing illicit trade markets and use existing data to reliably predict future illicit markets, it may be possible to isolate some of the key factors that may encourage or discourage

illicit trade in tobacco products. This draft concept paper assists that effort by breaking down the potential mechanics of an illicit trade market into various components, and examining the factors that could support or hinder the establishment of a persistent illicit trade market in the face of an FDA tobacco product standard. This paper first discusses the legal authority and general approach to establishing tobacco product standards, and then discusses the different components of illicit trade markets, followed by relevant research in consumer behavior and potentially applicable economic research.

FDA is providing notice and an opportunity to comment on this draft concept paper. Please provide evidence or other information supporting your comments.

II. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft concept paper at either <https://www.regulations.gov> or <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: March 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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