

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3261]

Modified Risk Tobacco Product Application: Application for Copenhagen® Snuff Fine Cut, a Loose Moist Snuff Tobacco Product Submitted by U.S. Smokeless Tobacco Company LLC

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of a modified risk tobacco product application (MRTPA) for Copenhagen® Snuff Fine Cut, a loose moist snuff tobacco product submitted by U.S. Smokeless Tobacco Co. LLC.

DATES: Electronic or written comments on the application may be submitted beginning September 21, 2018. FDA will establish a closing date for the comment period as described in section I.

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-3261 for "Application for Copenhagen® Snuff Fine Cut, a Loose Moist Snuff Tobacco Product Submitted by U.S. Smokeless Tobacco Company LLC." 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 dockets, 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 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.

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

SUPPLEMENTARY INFORMATION:

I. Background

Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k) addresses the marketing and distribution of MRTPs. MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any MRTP unless an order issued by FDA pursuant to section 911(g) of the FD&C Act is effective with respect to such product.

Section 911(d) of the FD&C Act describes the information that must be included in a MRTPA, which must be filed and evaluated by FDA before an applicant can receive an order from FDA. FDA is required by section 911(e) of the FD&C Act to make a MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911 of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (g)(2). The applicant, U.S. Smokeless Tobacco Co. LLC, is seeking an order under section 911(g)(1).

An order under section 911(g)(1) of the FD&C Act is for a modified risk tobacco product that significantly reduces harm and the risk of tobacco-related disease to individual tobacco users; and benefits the health of the population as a whole. A person seeking an order under section 911(g)(1) of the FD&C Act must show that the tobacco product, as it is actually used by consumers, will significantly reduce

harm and the risk of tobacco-related disease to individual tobacco users and will benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product benefits the health of individuals and the population as a whole.

FDA is issuing this notice to inform the public that a MRTPA for Copenhagen® Snuff Fine Cut submitted by U.S. Smokeless Tobacco Co. LLC has been filed and is being made available for public comment.

MR0000108: Copenhagen® Snuff Fine Cut

FDA will post the application documents, including any amendments, for public comment in batches on a rolling basis as they are redacted in accordance with applicable laws. In this document, FDA is announcing the availability of the first batch of application documents. FDA intends to establish a closing date for the comment period that is both at least 180 days after the date of this notice and at least 30 days after the final documents from the application are made available for public comment. FDA will announce the closing date at least 30 days in advance. FDA believes that this comment period is appropriate given the volume and complexity of the application being posted. FDA will notify the public about the availability of additional application documents and the comment period closing date via the Agency's web page for the MRTPA (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. To receive email alerts, visit FDA's email subscription service management website (<http://go.fda.gov/subscriptionmanagement>), provide an email address, scroll down to the "Tobacco" heading, select "Modified Risk Tobacco Product Application Updates", and click "Submit". To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

II. Electronic Access

Persons with access to the internet may obtain the documents at either <https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/>

[ucm619683.htm](http://www.regulations.gov/ucm619683.htm) or <https://www.regulations.gov>.

Dated: September 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20562 Filed 9–20–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0787]

Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Draft Guidance for Food and Drug Administration Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to the Food and Drug Administration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Draft Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA." The draft guidance provides the current thinking of FDA's Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH) regarding civil money penalties that may be assessed against responsible parties and/or submitters of certain applications and submissions to FDA regarding drug products, biological products, and device products who violate applicable Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibitions relating to requirements, including implementing regulations, submitting registration and/or results information to the *ClinicalTrials.gov* data bank, and/or certain certifications to FDA.

DATES: Submit either electronic or written comments on the draft guidance by November 20, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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").

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- 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–D–0787 for "Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Draft Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA." 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