

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]

**BILLING CODE 4164–01–P**

## 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").

#### *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–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

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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Patrick McNeilly, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire

Avenue, Bldg. 32, Rm. 5172, Silver Spring, MD 20993-0002, 301-796-2941.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA 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 CDER, CBER, and CDRH (Center, or collectively Centers), regarding civil money penalties for responsible parties and/or submitters of certain applications and submissions to FDA regarding drug products, biological products, or device products (submitters) who violate applicable FD&C Act (21 U.S.C. 301 *et seq.*) prohibitions relating to requirements under section 402(j) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)), including its implementing regulations in 42 CFR part 11, to submit registration and/or results information to the *ClinicalTrials.gov* data bank and/or certain certifications to FDA. The draft guidance is intended to address several questions. First, how the Centers identify whether responsible parties have failed to submit required clinical trial registration and/or results information to the *ClinicalTrials.gov* data bank or submitted false or misleading information to the data bank, and whether submitters have failed to submit the certification required by section 402(j)(5)(B) of the PHS Act (42 U.S.C. 282(j)(5)(B)) to FDA or knowingly submitted a false certification to FDA. Second, under what circumstances a Center may decide to seek civil money penalties against a responsible party or submitter. Third, what procedures apply when a Center seeks civil money penalties; and finally, what civil money penalty amounts may be assessed for: (1) Failing to submit required clinical trial registration and/or results information to the *ClinicalTrials.gov* data bank, (2) knowingly submitting false or misleading clinical trial information to the data bank, (3) failing to submit the required certification to FDA, or (4) knowingly submitting a false certification to FDA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on civil money penalties relating to the *ClinicalTrials.gov* data bank. It does not establish any rights for any person and is not binding on FDA or the public.

You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

##### **II. Electronic Access**

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: September 17, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-20560 Filed 9-20-18; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Evaluation and Implementation of Patient Care.

*Date:* October 11, 2018.

*Time:* 10:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Capital Skyline Hotel, 10 I Street SW, Washington, DC 20024.

*Contact Person:* Gabriel B. Fosu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, MSC 7808, Bethesda, MD 20892, (301) 435-3562, [fosug@csr.nih.gov](mailto:fosug@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Academic-Industrial Partnerships Research for Cancer Diagnosis and Treatment.

*Date:* October 15-16, 2018.

*Time:* 8:00 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.