optimizing trial quality, which promote the reliability, efficiency, and patient focus of clinical trials. This involves identifying the factors that are critical to the quality of a clinical trial at the design stage and planning the trial conduct proportionate to the risks to these quality factors, thereby protecting human subjects and ensuring the reliability of trial results. To resolve these issues, the ICH Assembly initiated a revision of the ICH E8 Guideline in November 2017 to provide updated guidance that is both appropriate and flexible enough to address the increasing diversity of clinical trial designs and data sources being employed to support regulatory and other health policy decisions, while retaining the underlying principles of human subject protection and data quality.

II. Topics for Discussion at the Public Meeting

The draft revised ICH E8 Guideline was endorsed by the ICH Assembly in May 2019 and made available for public comment. In the **Federal Register** of August 1, 2019 (84 FR 37649), FDA published a notice announcing the availability of a draft guidance entitled ''E8(R1) General Considerations for Clinical Studies'' (ICH E8(R1) Guideline) (available at *https://www.fda.gov/media/129527/download*). The notice gave interested persons an opportunity to submit comments by September 30, 2019. As part of a broader outreach process, ICH is holding public meetings before the finalization of the revised ICH E8(R1) Guideline. One of these public meetings will be hosted by FDA in Silver Spring, MD, on October 31, 2019 (see **DATES** and **ADDRESSES**). The purpose of the public meeting is to provide an overview of the new concepts presented in the revised ICH E8(R1) Guideline, allow for stakeholders who will be affected by the revised guideline to share their perspective, and allow for public input.

Public consultation is a standard part of all ICH guideline development, and it is conducted within each region of ICH Regulatory Members who commit to adoption of the finalized ICH guideline. This meeting is part of the ICH ''Good Clinical Practice (GCP) Renovation'' strategy to update the ICH guidelines related to clinical trial design, planning, management, and conduct, starting with the revision of the ICH E8 Guideline and followed by the revision of the ICH E6 Guideline for Good Clinical Practice. For more information, see the document ''ICH Reflection on 'GCP Renovation': Modernization of ICH E8 and Subsequent Renovation of ICH E6,'' available at *https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Reflection_Papers/ICH_Reflection_paper_GCP_Renovation_Jan_2017_Final.pdf.*

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by October 25, 2019, 11:59 p.m. Eastern Time. To register for the public meeting, please visit the following website: *https://globalichmeeting_e8r1_2019_americas.eventbrite.com.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

The agenda for the public meeting is available on the internet and can be viewed at the following link: *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/ich-global-meeting-ich-e8r1-guideline-general-considerations-clinical-trials-10312019-10312019.*

If you need special accommodations due to a disability, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) no later than October 18, 2019.

Requests for Oral Presentations: If you wish to make a presentation during the public comment session, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) no later than October 18, 2019. Presentation slots may be limited and will be granted on a first-come, first-served basis. Any public presentations should be limited to 5 minutes or less. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. If selected for presentation, any presentation materials must be emailed to Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) no later than October 24, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting. Signup for making a public comment during the meeting will also be available between 8 a.m. and 8:30 a.m. on the day of the meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast through the following link: *https://collaboration.fda.gov/ich103119/.* To register to attend via webcast, please visit the following website: *https://globalichmeeting_e8r1_2019_americas.eventbrite.com.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: September 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20935 Filed 9–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0994]

Modified Risk Tobacco Product Applications for VLN™ King and VLN™ Menthol King, Combusted, Filtered Cigarettes, Submitted by 22nd Century Group, Inc.; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; correction.

SUMMARY: The Food and Drug Administration is correcting a document entitled ''Modified Risk Tobacco Product Applications for VLN™ King and VLN™ Menthol King, Combusted, Filtered Cigarettes, Submitted by 22nd Century Group, Inc.'' that published in the **Federal Register** of July 25, 2019. The document announced the availability of modified risk tobacco product applications for public comment. The document published with incorrect submission tracking numbers. This document corrects that error.

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, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 25, 2019 (84 FR 35869), in FR Doc. 2019–15831, appearing on page 35869, the following correction is made:

1. On page 35870, in the third column, in the third full paragraph, the submission tracking numbers ''MR0000140: VLN™'' and

''MR0000141: VLN™ Menthol King'' are corrected to read ''MR0000159: VLN™'' and ''MR0000160: VLN™ Menthol King''.

Dated: September 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20899 Filed 9–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3769]

Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act.'' Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the FDA Reauthorization Act of 2017 (FDARA) require that certain presubmissions and submissions for devices be submitted in electronic format specified by FDA beginning on such date as specified in final guidance. It also mandates that FDA issue draft guidance not later than October 1, 2019, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements. In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter from the Secretary of Health and Human Services to Congress, FDA committed to developing electronic submission templates and issuing a draft guidance on the topic. This guidance is intended to satisfy the draft guidance documents referenced in FDA regulations and the MDUFA IV Commitment Letter. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 25, 2019 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–2019–D–3769 for ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food