Description: The proposed collection is a continuation of the current collection and comprised of two components: An application including a strategic plan that is due once every five years, and an annual self-assessment. The next collection (annual self-assessment) will be due June 30, 2020. The next five-year application will be due in 2021.

Respondents: We anticipate the highest state court of every state, Puerto Rico and the US Virgin Islands to respond. All 52 jurisdictions currently participate in the program.

ANNUAL BURDEN ESTIMATES

Collection	Year	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Complete Application	2021	52	1	92	4784
Complete Program Assessment Report	2020	52	1	77	4004
	2021	52	1	77	4004
	2022	52	1	77	4004
Total					16,796

Estimated Total Annual Burden Hours: 4004 hours in 2020 and 2022; 8788 hours in 2021 (when both the self-assessment and the 5-year application are due within the year)

Authority: Sec. 50761, P.L. 115–123.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–20890 Filed 9–25–19; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3935]

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Global Meeting on E8(R1) Guideline on General Considerations for Clinical Trials; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting entitled ''International Council on Harmonisation (ICH) Global Meeting on E8(R1) Guideline on General Considerations for Clinical Trials.'' The purpose of the public meeting is to provide information on the draft revised E8(R1) Guideline ''General Considerations for Clinical Trials'' (ICH E8 Guideline) following the closing of the FDA comment period and closing of the regional consultations conducted in other ICH regions. The ICH E8 Guideline is being revised 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.

DATES: The public meeting will be held on Thursday, October 31, 2019, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1503 (the Great Room), Silver Spring, MD 20993–0002. The meeting will also be broadcast on the web, allowing participants to join in person or via the web. For those who will attend in person, the entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* For those who register to attend the public meeting remotely via the webcast, a link to access the webcast will be emailed in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–4548, Amanda.Roache@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory requirements for safety and effectiveness. One of the goals of harmonization is to identify and then reduce regional differences in technical regulatory requirements for pharmaceutical products while preserving a consistently high standard for drug efficacy, safety, and quality. This is accomplished through the development of internationally harmonized guidelines developed through a process of scientific consensus with regulatory and industry experts. FDA participates in ICH as a founding member and implements all ICH guidelines as FDA guidance.

In 2015, ICH was reformed to establish it as a true global initiative and to expand beyond the previous ICH members. More involvement from regulators around the world is expected, as they join counterparts from Europe, Japan, the United States, Canada, and Switzerland as ICH regulatory members and observers. Expanded involvement is also anticipated from global regulated pharmaceutical industry parties, joining as ICH industry members and observers. The reforms built on a 25-year track record and have allowed ICH to continue its successful delivery of harmonized guidelines for global pharmaceutical development and their regulation.

The ICH E8 Guideline sets out general principles on the conduct of clinical trials, was adopted in 1997, and has not undergone revision. Since its adoption, clinical trial design and conduct have become more complex, impacting the time and cost required to develop drugs. A wide range of both trial designs and data sources play a role in drug development and are not adequately addressed in the original ICH E8 Guideline. Approaches are needed for

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