4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0602]

Electronic Submission of Tobacco Product Applications and Other Information; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is announcing a 1-day workshop to obtain public input on topics related to the potential electronic submission of tobacco product applications and other information. This workshop will focus on the technical aspects of electronic submissions, including potential standards for content, format, and structure. The input from the public workshop may assist the Agency in the potential development and implementation of an electronic submission standard for CTP. FDA is also opening a public docket to receive comments on this topic.

Date and Time: The public workshop will be held on July 18, 2013, from 9 a.m. to 3 p.m. Individuals who wish to attend, participate in, or view the free Webcast of the public workshop must register by 5 p.m. EDT on June 21, 2013. Submit either electronic or written comments to the docket by August 19, 2013.

Location: The public workshop will be held at 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373.

Contact Person: Karen M. Templeton-Somers, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850, 1-877-287-1373, FAX: 240-276-3655, email: workshop.CTPOS@fda.hhs.gov.

Registration to Attend the Workshop: If you wish to attend the workshop, make an oral presentation at the workshop, or view the free Webcast, you must register by submitting an electronic or written request by 5 p.m. EDT on June 21, 2013. Submit electronic requests to http://www.surveymonkey.com/s/HWY9KNC. A confirmation email will be sent to your registered email address at least 2 weeks prior to the workshop date. Those without email access may register by contacting Karen M. Templeton-Somers (see Contact Person). Registration is free, but early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Onsite registration on the day of the workshop will be based on space availability. CTP plans to provide a free-of-charge, live Webcast of the workshop. Please note that the Webcast link will not be live until the meeting begins at approximately 9 a.m. EDT on July 18, 2013. If registration reaches maximum capacity, FDA will post a notice closing registration for the workshop at http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm.

Requests for Oral Presentations: If you wish to make an oral presentation, please state your intention on your registration submission and submit your name, title, company or organization (if applicable), address, telephone number, and email address. FDA has included specific topics for discussion in section II of this document. You should identify by number each discussion topic(s) you wish to address in your presentation, and the approximate desired length of your presentation. FDA is interested in obtaining input from a range of stakeholders and

interested parties, including, but not limited to, large and small pharmaceutical manufacturers experienced with electronic Common Technical Document (eCTD); vendors of software used to support electronic submissions; and large and small tobacco product manufacturers. Individuals and organizations with common interests are urged to coordinate their presentations or request time for a joint presentation. All requests to make oral presentations must be received by the close of registration at 5 p.m. EDT on June 21, 2013. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by June 28, 2013. Presenters must submit any presentation materials to Karen M. Templeton-Somers (see Contact Person) via email no later than July 10, 2013. FDA will do its best to accommodate questions during the workshop, although questions from the audience may be limited. In addition, we strongly encourage submitting comments to the docket (see Comments).

If you need special accommodations because of disability, please contact Karen M. Templeton-Somers (see Contact Person) at least 7 days before the workshop.

Comments: Regardless of attendance at the public workshop, interested persons may submit comments on any of the topics for discussion in section II of this document by August 19, 2013. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Workshop Topics

The purpose of this workshop is to obtain public input from regulated industry and other stakeholders and interested parties on the potential development and implementation of a standardized structure for electronic submission of tobacco product applications and other information. Stakeholders and interested parties could include, but are not limited to, large and small pharmaceutical manufacturers with experience in electronic submissions; vendors of software used to support electronic submissions; and large and small tobacco product manufacturers. The workshop will focus on technical aspects related to electronic submissions and standards currently used in other FDA centers. The types of submissions potentially subject to any future electronic submission standard may include, but are not limited to, applications for premarket review of new tobacco products (section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act) (the FD&C Act) (21 U.S.C. 387j(b)(1)), modified risk tobacco product applications (section 911(d) of the FD&C Act (21 U.S.C. 387k(d)), and reports submitted under section 905(j) of the FD&C Act (21 U.S.C 387e(j)). In particular, FDA would like to discuss how available standardized submission structure and technologies facilitate preparation, submission, retrieval, processing, review, and archiving of submissions. For more information on study data standards resources, please see http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm.

The electronic submission workshop will include discussion on eCTD, which is an International Conference on Harmonization (ICH) specification developed by ICH and its member parties. The eCTD provides an organizational structure for regulatory submissions utilizing comprehensive table of contents headings and hierarchy. Other FDA centers have been

receiving submissions in the eCTD format since 2003. For more information on eCTD, please see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.

CTP is interested in receiving input at the workshop and in the docket on the potential standardization of electronic tobacco product submissions. The input from the workshop may assist the Agency in developing and implementing a harmonized electronic submission standard at CTP.

II. Workshop Topics for Discussion

FDA is seeking public input on the following topics:

- How have other regulated industries standardized the structure of submissions to FDA and how has that facilitated the submission and review process? What aspects may be applicable to tobacco product submissions?
- What technologies do tobacco companies currently use to prepare their submissions? Is a document management system used? Are specific technologies used? Is electronic data capture used in clinical trials or other studies? What systems and standards currently are used to manage data and documents?
- How are data collected and managed for submission to CTP? Is a laboratory information management system used?
- Are there any technical limitations CTP should consider in developing and implementing any harmonized electronic submission standard?
- Would a pilot program designed to test a modified eCTD be useful?

Dated June 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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