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 Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Kevin Rice, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0680, *kevin.rice@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GIF #242 entitled ''In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products.'' The purpose of in-use stability testing is to establish a period of time during which a multiple-dose drug product may be used while retaining acceptable quality specifications once the container is opened (*e.g.,* after a container has been needle-punctured). This draft guidance reflects the Agency's current thinking on how to formulate in-use statements, as well as how to design and carry out in-use stability studies to support these in-use statements, for multiple-dose injectable drug products intended for use in animals. This current thinking pertains to both generic drug products and pioneer drug products regardless of whether or not the pioneer RLNAD currently has an in-use statement on the labeling.

II. Significance of Guidance

This level 1 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 ''In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products.'' 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032. The collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117. The collections of information in sections 512(b) and (n) of the Federal Food, Drug, and Cosmetic Act have been approved under OMB control number 0910–0669.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov*.

Dated: December 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31855 Filed 1–3–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4232]

Battery Safety Concerns in Electronic Nicotine Delivery Systems; Public Workshop; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Public workshop; establishment of public docket; request for data, information, and comments.

SUMMARY: The Food and Drug Administration (FDA) Center for Tobacco Products (CTP) is announcing several actions concerning issues related to batteries used in electronic nicotine delivery systems (ENDS), including electronic cigarettes (e-cigarettes). These actions are intended to give CTP staff an opportunity to hear from the public, including tobacco product manufacturers, importers, researchers, and academic investigators, about ENDS battery safety concerns (*e.g.,* overheating, fire, explosion), risk mitigation, and design parameters. Additionally, FDA is interested in information related to communication to consumers and the general public related to ENDS battery safety concerns. FDA is announcing a public workshop on ENDS batteries and safety hazards. The 2-day public workshop will include presentations and panel discussions about ENDS battery safety concerns as well as how potential safety hazards and risks are communicated to consumers and the general public. In conjunction with the public workshop, FDA is establishing a public docket to gather data and information on hazards and risks associated with the use of batteries in ENDS. Regardless of attendance at the public workshop, interested parties are invited to submit comments, including data and research.

DATES: The public workshop will be held on April 19 and 20, 2017, from 8:30 a.m. to 4:30 p.m. Individuals who wish to attend the public workshop must register by March 17, 2017. Electronic or written comments to the docket will be accepted until May 22, 2017.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine

security check procedures will be performed. For parking, transportation, security, and information regarding special accommodations due to a disability, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

You may submit comments to the public docket 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–4232 for ''Battery Safety Concerns in Electronic Nicotine Delivery Systems (ENDS) Public Workshop; Establishment of a Public Docket; Request for Comments.'' 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 Division of Dockets Management 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 Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joanna Randazzo, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4411A, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act), amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing. The FD&C Act also gives FDA the ability, through rulemaking, to regulate additional products that meet the legal definition of a tobacco product. On May 10, 2016, FDA published a final rule entitled ''Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (81 FR 28974) that became effective on August 8, 2016. Under this rule, newly deemed tobacco products, such as ENDS, are now subject to the provisions of the Tobacco Control Act that apply automatically to all products that meet the statutory definition of a tobacco product in section 201(rr) of the FD&C Act.

FDA has become aware of recent reports of battery-related safety events such as exploding batteries in ENDS, which include e-cigarettes. As a result, FDA is interested in gaining knowledge about ENDS battery safety hazards and controls, including internal and external battery-related factors, specifications, safety, and design parameters of the ENDS apparatus. In addition, FDA is interested in understanding how these risks currently are communicated to consumers, as well as how they may be communicated in the future, in an effort to determine the most effective method to address these problems. FDA is announcing a public workshop and establishing a public docket to gather data and information on hazards and risks associated with the use of batteries in ENDS. Regardless of attendance at the public workshop, interested parties are invited to submit comments, supported by research and data, regarding the topics for discussion at the public workshop (see section II). Information related to workshop presentations and discussion topics, including specific questions to be addressed at the workshop, can be found at *http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm*. The information gathered through this public docket may be used by FDA in considering future actions.

II. Public Workshop on Battery Safety Concerns in ENDS

FDA is announcing a 2-day public workshop to gather scientific information and stimulate discussion about hazards and risks associated with

the use of batteries in ENDS, including e-cigarettes. In particular, the workshop seeks to gather information, including research and data, on: (1) ENDS battery safety concerns (*e.g.,* overheating, fire, explosion, other modes of failure); (2) factors that contribute to ENDS battery failures; and (3) information on ENDS design features and other parameters that may impact the occurrence of these failures. The workshop is intended to better inform FDA about the hazards and risks associated with the use of batteries in ENDS. FDA is seeking input from a broad group of stakeholders, including, but not limited to: Scientific and medical experts; ENDS manufacturers, importers, distributors, wholesalers, and retailers; manufacturers of batteries for ENDS and other consumer products; state, and local government agencies; and other interested stakeholders, such as academic researchers and public health organizations.

Topics for Discussion: The public workshop will include presentations and panel discussions regarding substantive scientific information, specifically relating to hazards and risks associated with the use of batteries in ENDS, including e-cigarettes. Topics to be addressed include, for example: (1) Factors that contribute to failure of rechargeable and non-rechargeable ENDS batteries resulting in overheating, fire, explosion, or other modes of failure (this may include factors relating to batteries, charging equipment, components and parts such as voltage and temperature controllers or other circuitry, other ENDS design features, user modification of ENDS, and e-liquids), and what influence these factors have on the mode of failure (*e.g.,* battery overheating versus explosion); (2) safety features (*e.g.,* circuit protection, charging safety features) and battery standards that may be applied to ENDS batteries to limit their potential for overheating, fire, explosion, or other mode of failure; (3) changes, improvements, and innovations to battery and ENDS design that would limit the potential for overheating, fire, explosion, or other mode of failure; (4) other public health risks associated with ENDS batteries (*e.g.,* leakage); (5) ENDS design changes that could mitigate public health risks upon battery failure; (6) battery safety information that is communicated to ENDS consumers and the general public; and (7) best practices to effectively communicate potential risks associated with ENDS batteries to consumers and the general public (*e.g.,* via labeling, instructions for use, warnings). Additional information related to workshop presentations and discussions topics, including specific questions, can be found at *http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm*.

Attendance and Registration: To attend the workshop in person or by Webcast, individuals must register by submitting either an electronic or written request no later than March 17, 2017. Please submit electronic requests to register at *https://www.surveymonkey.com/r/FDACTP_ENDS_Battery_Workshop*. Persons without Internet access may send written requests for registration to Dhanya John, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Building 71, Rm. G335, Silver Spring, MD 20993–0002. Requests for registration must include the prospective attendee's name, title, affiliation, address, email address if available, and telephone number. Registration is free and you may register to either attend in-person or view the live Webcast. For registrants with Internet access, confirmation of registration will be emailed to you no later than March 21, 2017. For additional information regarding public workshop location and attendance capacities please refer to *http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm*.

Presenters and Panelists: FDA is interested in gathering scientific information from individuals with a broad range of perspectives on technical topics to be discussed at the workshop. To be considered to serve as a presenter, please provide the following:

- A brief abstract for each presentation: The abstract should identify the specific topic(s) to be addressed and the amount of time requested.
- A one-page biosketch that describes and supports your scientific expertise on the specific topic(s) being presented, nature of your experience and research in the scientific field, positions held, and any program development activities.

Panelists will discuss their scientific knowledge on the questions and presentations in each session. To be considered to serve as a panelist, please provide a one-page biosketch that describes and supports your scientific expertise on the specific topic(s) being presented, nature of your experience and research in the scientific field, positions held, and any program development activities.

If you are interested in serving as a presenter or a panelist, please submit the above information, along with the topic(s) on which you would like to speak, to *workshop.CTPOS@fda.hhs.gov* by February 17, 2017.

Oral Presentations by Members of the Public: This workshop will include a public comment session. Persons wishing to present during the public comment session must make this request at the time of registration and should identify the topic they wish to address from among those topics under consideration, which are identified in section II of this document. FDA will do its best to accommodate requests to present. FDA urges individuals and organizations with common interests to consolidate or coordinate their comments, and request a single time for a joint presentation. Requesters with Internet access and who have submitted a working email address will receive an email regarding their request to speak during the public comment session by March 21, 2017.

Transcripts: A transcript of the proceedings will be available after the workshop at *http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm* as soon as the official transcript is finalized. It also will be posted to the docket at *https://www.regulations.gov*.

III. Additional Opportunities To Speak With FDA

As is always the case, we welcome entities interested in meeting with FDA to discuss any of these ENDS battery safety topics to contact FDA directly. To facilitate such meetings, you may submit requests for an informal meeting to the attention of the Director, Office of Science, CTP, via email to *AskCTP@fda.hhs.gov* or U.S. mail to the following address: Food and Drug Administration, Center for Tobacco Products, Document Control Center, 10903 New Hampshire Ave., Building 71, Rm. G335, Silver Spring, MD 20993–0002. Please prominently identify your request as ''ENDS battery informal meeting.'' Please refer to section II for more information regarding submitting comments to the public docket.

Dated: December 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31857 Filed 1–3–17; 8:45 am]

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