

committee is a non-discretionary Federal advisory committee established to provide advice and consultation to the Commissioner. The Commissioner of Food and Drugs is charged with the administration of the Radiation Control for Health and Safety Act of 1968. This Act creates the Technical Electronic Product Radiation Safety Standards Committee and requires the Commissioner to consult with the Committee before prescribing standards for radiation emissions from electronic products. This Committee provides advice and consultation to the Commissioner of Food and Drugs on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products, and may recommend electronic product radiation safety standards to the Commissioner for consideration.

The Committee shall consist of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to 4 years. Terms of more than two years are contingent upon the renewal of the Committee by appropriate action prior to its expiration. The core of voting members will include five members selected from governmental agencies, including State and Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor. A quorum shall consist of 10 members, of which at least 3 shall be from the general public, 3 from the government agencies, and 3 from the affected industries.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/default.htm>, or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees,

please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: December 28, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–31847 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–D–4437]

#### In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products; Draft Guidance for Industry; 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 (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 reference listed new animal drug (RLNAD) currently has an in-use statement on the labeling.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 6, 2017.

**ADDRESSES:** You may submit comments 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–D–4437 for “In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products.” 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.

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](mailto: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.*

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**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