

The Agency encourages individuals, industry, device manufacturers, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop. Workshop updates will be made available on the internet at <http://www.fda.gov/Drugs/NewsEvents/ucm512519.htm>.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available either in hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>. Transcripts will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm512519.htm> approximately 45 days after the workshop.

Dated: September 9, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2004-D-0045]

#### Waivers From the Requirement To Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles; Draft Revised 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 revised guidance for industry (GFI) #171 entitled "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." This draft revised guidance document describes how the Center for Veterinary Medicine (CVM) intends to evaluate requests for waiving the requirement for submitting data demonstrating the bioequivalence of animal drugs in soluble powder oral dosage form products and Type A medicated articles. It expands upon

CVM's Bioequivalence Guidance,<sup>1</sup> particularly the section on Criteria for Waiver of In Vivo Bioequivalence Study. This guidance is applicable to generic investigational new animal drug (JINAD) files and abbreviated new animal drug applications (ANADAs). Although the recommendations in this guidance reference generic drug applications, the general principles described may also be applicable to new animal drug applications (NADAs), investigational new animal drug (INAD) files, and supplemental NADAs.

**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 revised guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft revised guidance by November 15, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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-2004-D-0045 for "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://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 <http://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 <http://www.regulations.gov> and insert the docket number, found in brackets in the

<sup>1</sup> CVM Guidance for Industry #35, "Bioequivalence Guidance," November 8, 2006 (see page 7): <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052363.pdf>.

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 revised guidance document.

**FOR FURTHER INFORMATION CONTACT:** Charli Long, Center for Veterinary Medicine (HFV-170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0850, [charli.long-medrano@fda.hhs.gov](mailto:charli.long-medrano@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft revised guidance for industry #171 entitled "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." This draft revised guidance document describes how the Center for Veterinary Medicine (CVM) intends to evaluate requests for waiving the requirement for submitting data demonstrating the bioequivalence of animal drugs in soluble powder oral dosage form products and Type A medicated articles. It expands upon CVM's Bioequivalence Guidance,<sup>2</sup> particularly the section on Criteria for Waiver of In Vivo Bioequivalence Study. This draft revised guidance document is intended to provide clarification of the scientific basis for concepts and recommendations conveyed in the original guidance. In addition, the table containing estimated gastric volumes for each of the various animal species has been revised. However, applicants may propose an alternative gastric volume value for a particular species when using the dosage adjusted approach. No new concepts have been introduced in this draft revised guidance and its scope has not been modified.

**II. Significance of Guidance**

This level 1 draft revised guidance is being issued consistent with FDA's good

<sup>2</sup> CVM Guidance for Industry #35, "Bioequivalence Guidance," November 8, 2006 (see page 7): <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052363.pdf>.

guidance practices regulation (21 CFR 10.115). The draft revised guidance, when finalized, will represent the current thinking of FDA on "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." 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 revised guidance refers to previously approved collections of information that 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 referred to in the guidance entitled "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles" have been approved under OMB control number 0910-0575.

**IV. Electronic Access**

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

Dated: September 9, 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-0001]

**Menu Labeling Public Workshop; Public Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing a third public meeting to discuss menu labeling requirements. We announced the first two public meetings in a separate **Federal Register** notice earlier this year. The purpose of the public meetings is to help the regulated industry comply with the requirements of the menu labeling final rule.

**DATES:** See "How to Participate in the Public Meeting" in the **SUPPLEMENTARY INFORMATION** section of this document for dates, times, and addresses of the public meeting, closing date for advance registration, requesting special accommodations due to disability, and other information.

**ADDRESSES:** See "How to Participate in the Public Meeting" in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** For questions about registering for this meeting or for special accommodations due to disability, contact Cindy de Sales, The Event Planning Group, 8720 Georgia Ave., Suite 801, Silver Spring, MD 20910, 240-316-3207, FAX: 240-652-6002, email: [rsvp@tepgevents.com](mailto:rsvp@tepgevents.com).

For general questions about the public meeting, contact Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of December 1, 2014 (79 FR 71156), we published a final rule on nutrition labeling of standard menu items in restaurants and similar retail food establishments; the rule is codified at Title 21 of the *Code of Federal Regulations*, section 101.11. The final rule implements section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)(5)(H)), which, in general, requires that restaurants and similar retail food establishments that are part of a chain with 20 or more locations, doing business under the same name, and offering for sale substantially the same menu items, provide calorie information for standard menu items (including food on display and self-service food); provide, upon request, additional written nutrition information for standard menu items; and comply with other requirements described in section 403(q)(5)(H) of the FD&C Act.

On December 18, 2015, the President signed the Consolidated Appropriations Act, 2016 (Pub. L. 114-113). Section 747 of the Consolidated Appropriations Act states that none of the funds made available under the Consolidated Appropriations Act may be used to implement, administer, or enforce the final rule entitled "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments" until 1 year after the date of publication of a Level 1 guidance with respect to nutrition labeling of standard menu items in