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.*

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,[2] 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 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.

[FR Doc. 2016–22339 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

[2] CVM Guidance for Industry #35, ''Bioequivalence Guidance,'' November 8, 2006 (see page 7): *http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052363.pdf.*

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.*

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

restaurants and similar retail food establishments.

In the **Federal Register** of May 5, 2016 (81 FR 27067), we announced the availability of the guidance for industry entitled ''A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11).'' The guidance uses a question and answer format and is intended to help restaurants and similar retail food establishments covered by the final rule comply with the nutrition labeling requirements of the final rule. In accordance with the Consolidated Appropriations Act, 2016, enforcement of the final rule will commence May 5, 2017.

We have made education of the menu labeling requirements a high priority, and this is our third menu labeling workshop to educate interested members of the public, especially the regulated industry, about the menu labeling requirements. We announced the first two public meetings in a separate **Federal Register** notice on June 15, 2016 (81 FR 39056). Interested persons can continue to submit general questions to *CalorieLabeling@fda.hhs.gov.*

II. Purpose and Format of the Public Meeting

The purpose of this public meeting is to help the regulated industry comply with the requirements of the menu labeling final rule. On the morning of day one of the meeting, we will give a slide presentation on the menu labeling requirements. (Please note the slide presentation will only be presented on day one.) The afternoon of day one and all of day two will consist of consultation sessions with FDA staff where individual companies (limited to two members per company) may discuss their specific questions and concerns. Each consultation session is limited to 15 minutes to help ensure that enough time is available to accommodate each company that requests a consultation. We recommend that participants in the consultation session prepare their questions in advance due to the limited time available.

III. How To Participate in the Public Meeting

We encourage all persons who wish to attend the meeting to register in advance of the meeting and to indicate whether they are requesting a consultation session. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. Early registration is recommended to facilitate planning of the consultation sessions and because seating is limited. We encourage you to use electronic registration if possible (see the address in table 1).

Table 1 provides information on participation in the public meeting.

TABLE 1—INFORMATION ON MENU LABELING MEETING

Activity	Date	Electronic address	Address
Public meeting	November 16 and 17, 2016, 8 a.m. to 4:30 p.m.		Holiday Inn Hotel & Suites Oakland Airport, 77 Hegenberger Rd., Oakland, CA 94621.
Advance registration	by November 9, 2016	*http://www.cvent.com/d/zfq6sm*	We encourage you to use electronic registration if possible.[1]
Request special accommodations due to a disability.	by November 9, 2016		See **FOR FURTHER INFORMATION CONTACT**.

[1] You may also register via mail, fax, or email. Please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: 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.*

IV. Transcripts

Transcripts of the workshop will not be prepared.

Dated: September 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22337 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a virtual meeting of the Frederick National Laboratory Advisory Committee to the National Cancer Institute.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will also be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov/*).

Name of Committee: Frederick National Laboratory Advisory Committee to the National Cancer Institute.

Date: October 21, 2016.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: Report from the FNLAC RAS Workgroup.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room TE406, Rockville, MD 20850, (Virtual Meeting).

Contact Person: Peter L. Wirth, Ph.D., Executive Secretary, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 7W514, Bethesda, MD 20892, 240–276–6434, *wirthp@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NCI Shady Grove has instituted stringent procedures for entrance into the NCI Shady Grove building. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/fac/fac.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)