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 convey 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.


Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164–01–P

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.
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 for 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>
<thead>
<tr>
<th>Activity</th>
<th>Date</th>
<th>Electronic address</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public meeting</td>
<td>November 16 and 17, 2016, 8 a.m. to 4:30 p.m.</td>
<td><a href="http://www.cvent.com/d/zfq6sm">http://www.cvent.com/d/zfq6sm</a></td>
<td>Holiday Inn Hotel &amp; Suites Oakland Airport, 77 Hegenberger Rd., Oakland, CA 94621.</td>
</tr>
<tr>
<td>Advance registration</td>
<td>by November 9, 2016</td>
<td></td>
<td>We encourage you to use electronic registration if possible. See FOR FURTHER INFORMATION CONTACT.</td>
</tr>
<tr>
<td>Request special accommodations due to a disability.</td>
<td>by November 9, 2016</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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]

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 video cast 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 Mappor; 93.399, Cancer Control, National Institutes of Health, HHS)