TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS—Continued

	Date	Electronic address	Address (non-electronic)	Other information
Make a request for oral presentation.	Submit a request by November 10, 2011.	*http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	.....	Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to *http://www.regulations.gov,* including any personal information provided.
Provide a brief description of the oral presentation and any written material for the presentation.	By November 21, 2011	*http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	.....	Written material associated with an oral presentation should be submitted in Microsoft PowerPoint, Microsoft Word, or Adobe Portable Document Format (PDF) and may be posted without change to *http://www.regulations.gov,* including any personal information provided.
Submit electronic or written comments.	Submit comments by January 30, 2012.	Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.	Fax: 301–827–6870, Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.	All comments must include the Agency name and the docket number corresponding to the Cosmetic Microbiological Safety Issues; Public Meeting. All received comments may be posted without change to *http://www.regulations.gov,* including any personal information provided. FDA encourages the submission of electronic comments by using the Federal eRulemaking Portal. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

IV. Comments

Regardless of attendance at the public meeting, interested persons may submit to the Division of Dockets management (see Table 1 of this document) either electronic or written comments for consideration at or after the meeting in addition to, or in place of, a request for an opportunity to make an oral presentation. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be viewed in the Division of Dockets Management at the address provided in Table 1 of this document between 9 a.m. and 4 p.m., Monday through Friday.

V. References

We have placed hard copies of the following references on display in the Division of Dockets Management (see **ADDRESSES**). You may view them between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.)

1. FDA, ''Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist,'' available at *http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GoodManufacturingPracticeGMPGuidelinesInspectionChecklist/default.htm.*

2. FDA, ''Cosmetic Labeling Manual,'' available at *http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/CosmeticLabelingManual/default.htm.*

3. FDA, ''Guidance Documents,'' available at *http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/default.htm.*

4. FDA, Bacteriological Analytical Manual, chapter 23, ''Microbiological Methods for Cosmetics,'' available at *http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/ucm073598.htm.*

VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov* and at FDA's Web site under ''Cosmetics.'' It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after the submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: October 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–28238 Filed 10–31–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0754]

Pediatric Medical Devices; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Using Scientific Research Data to Support Pediatric Medical Device Claims: A Public Dialogue.'' The purpose of the public workshop is to receive public comment on the use of scientific research data, including published scientific literature, to support and establish pediatric indications for medical devices.

The topics to be discussed are: The ways scientific research data can be used to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance; the scientific and regulatory limitations and issues of using existing scientific research data to support pediatric effectiveness claims and pediatric indication approvals for medical devices; and methods to overcome the pitfalls and data gaps, including statistical approaches and modeling.

Date and Time: The public workshop will be held on December 5, 2011, from 8:30 a.m. to 5 p.m. EST.

Location: 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.

Contact Person: Carol Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5437, Silver Spring, MD 20993–0002, (301) 796–3241, *Carol.Krueger@fda.hhs.gov.*

Registration: Registration is free and on a first-come, first-served basis. Persons interested in attending this workshop must register online by 5 p.m. on November 28, 2011. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. If you need special accommodations due to a disability, please contact Cynthia Garris (*email: Cynthia.Garris@fda.hhs.gov* or (301) 796–5861) no later than November 28, 2011.

To register for the public workshop, please visit the following *Web site: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (or go the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Carol Krueger to register (see *Contact Person*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Web Cast of the Public Workshop: This workshop will also be Web cast. Persons interested in viewing the Web cast must register online by 5 p.m. on November 28, 2011. Early registration is recommended because Web cast connections are limited. Organizations are requested to register all participants but to view using one connection per location. Web cast participants will be sent technical system requirements after registration and will be sent connection access information after November 28th. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Workshop Format: This workshop is structured as topic-focused breakout sessions, intended to foster constructive dialogue between stakeholders with diverse perspectives. Moderators of each small group will summarize the group discussion and present it to the participants.

Comments: FDA is holding this public workshop to obtain information on a number of questions regarding factors affecting approval or clearance of devices for use with a pediatric population. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting written or electronic comments on all aspects of the workshop topics. The deadline for submitting comments related to this public workshop is January 5, 2012.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is necessary to send only one set of comments. It is no longer necessary to send two copies of mailed comments. Please identify written comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at *http://www.regulations.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 2007, Congress passed the Pediatric Medical Device Safety and Improvement Act (the Act). The Act addresses pediatric device needs by providing financial incentives for development, production, approval and distribution of new devices for rare and unmet pediatric needs; allowing for a pediatric device approval pathway that permits extrapolation of adult effectiveness data to support a pediatric indication based on similar course of the disease or condition or a similar effect of the device; and providing grants to pediatric device consortia that provide technical support and assistance to pediatric device innovators.

This workshop will support FDA's efforts to define pathways for approving pediatric device indications by leveraging available scientific research data. An important, but not the only, focus will be a discussion of how to determine when it is appropriate to use, and how to use, existing scientific research data to determine pediatric effectiveness based on a similar course of a disease or condition or a similar effect of a device on adults and similar extrapolation between pediatric subpopulations.

The demand by health care professionals and consumers for safe and effective pediatric medical devices continues to steadily increase. Pediatric medical devices treat or diagnose diseases and conditions occurring from birth through the 21st year of life. Some devices are designed specifically for pediatric use, while others are adopted from specific adult device applications or produced for more general use.

Designing pediatric medical devices can be challenging; children are often smaller and more active than adults, body structures and functions change throughout childhood, and children may be long-term device users—bringing new concerns about device longevity and long-term exposure to implanted materials. The current medical device market for children has a higher demand than supply. FDA is committed to supporting the development and availability of safe and effective pediatric medical devices.

Through this effort, FDA and stakeholders will take steps to increase awareness of a path for approval of pediatric devices that uses certain literature. FDA can advance this goal by collaborating with stakeholders, including medical device and health care industries, and the health care provider and consumer communities.

II. Topics for Discussion at the Public Workshop

The public workshop will be organized to discuss the following topic areas:

A. The use of existing scientific research data to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance,

B. The scientific and regulatory limitations and issues with the use of existing scientific research data, and

C. The methods to overcome the pitfalls and data gaps, including statistical approaches and modeling.

III. 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 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated: October 26, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–28244 Filed 10–31–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0238]

Preventive Controls for Registered Human Food and Animal Food/Feed Facilities; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice, published in the **Federal Register** of May 23, 2011 (76 FR 29767), entitled ''Preventive Controls for Registered Human Food and Animal Food/Feed Facilities; Request for Comments.'' In that document, FDA opened a docket and requested information about preventive controls and other practices used by facilities to identify and address hazards associated with specific types of food and specific processes. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by December 20, 2011.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, (240) 402–2166; or Kim Young, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–9207.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 23, 2011 (76 FR 29767), FDA published a notice with a 90-day comment period to obtain information about preventive controls and other practices used by facilities to identify and address hazards associated with specific types of food and specific processes. Information obtained will assist FDA in the development of guidance on preventive controls for food facilities that manufacture, process, pack, or hold human food or animal food/feed (including pet food).

The Agency has received a request for an extension of the comment period for this notice. FDA has considered the request and is extending the comment period for the notice entitled ''Preventive Controls for Registered Human Food and Animal Food/Feed Facilities; Request for Comments'' until December 20, 2011. The Agency believes that this extension allows adequate time for interested persons to submit comments without significantly delaying action by the Agency.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–28239 Filed 10–31–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on Public Advisory Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on certain device panels of the Medical Devices Advisory Committee (MDAC) in the Center for Devices and Radiological Health (CDRH) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on certain device panels of the MDAC in the CDRH. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organizations interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by December 1, 2011, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by December 1, 2011.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5234, Silver Spring, MD 20993, (301) 796–5960, *Fax:* (301) 847–8505, *email: margaret.ames@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 520(f)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include one nonvoting member to represent the interests of the medical device