TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					95,083

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of Record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through (e)(4)	5,000	75	375,000	.0167	6,263
Total					25,051

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the times required for record preparation and maintenance is based on Agency communication with industry and Agency records and experience.

Dated: October 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–28240 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–0770]

Cosmetic Microbiological Safety Issues; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments and opening of a docket.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Cosmetic Microbiological Safety Issues.'' The purpose of the public meeting is to provide stakeholders an opportunity to present information regarding cosmetic microbiological safety and to suggest areas for the possible development of FDA guidance documents. FDA is seeking information regarding microbiological testing of cosmetics; types of preservative systems and how to test their efficacy; the identity and prevalence of microorganisms, including antibiotic-resistant strains, that pose specific health risks in finished products; routes of exposure to microorganisms and the corresponding infective doses; product and packaging characteristics that affect microbial growth and risk of infection; particular subpopulations that may be at greater risk of infection when using different cosmetic products; the occurrence of adverse events associated with microbial contamination of cosmetics; and any other issues relevant to the microbiological safety of cosmetics.

DATES: Submit either electronic or written comments to FDA's Division of Dockets Management by January 30, 2012. See also ''How to Participate in the Meeting'' in the **SUPPLEMENTARY INFORMATION** section of this document for important meeting registration deadlines.

ADDRESSES: See Table 1 of this document for meeting location and other information regarding registration for this meeting.

FOR FURTHER INFORMATION CONTACT: For questions about registering for the meeting, to register orally, or to submit a notice of participation by mail, fax, or *email:* Courtney Treece, Planning Professionals, Ltd., 1210 W. McDermott, suite 111, Allen, TX 75013, (704) 258–4983. *Fax:* (469) 854–6992, *ctreece@planningprofessionals.com.*

For questions about the meeting, to request an opportunity to make public comments, to submit the full text, comprehensive outline, or summary of an oral presentation, or to request special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, (240) 402–1731, *Juanita.Yates@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA regulates cosmetics under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*) and, for products marketed on a retail basis to consumers, under the Fair Packaging and Labeling Act (FPLA) (15 U.S.C. 1451 *et seq.*). The law requires that cosmetics be neither adulterated under section 601 of the FD&C Act (21 U.S.C. 361) nor misbranded under section 602 of the FD&C Act (21 U.S.C. 362). That is, they must be safe for consumers under labeled or customary conditions of use and they must be properly labeled. FDA has issued regulations addressing certain aspects of cosmetic safety and labeling (see 21 CFR parts 700, 701, and 740). FDA has also issued guidance regarding certain aspects of cosmetic safety and labeling, including the ''Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist'' (available at *http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GoodManufacturingPracticeGMPGuidelinesInspectionChecklist/default.htm*), the ''Cosmetic Labeling Manual'' (available at *http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/CosmeticLabelingManual/default.htm*), and other cosmetic guidance documents (available at *http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/default.htm*).

FDA has not yet issued specific guidance regarding cosmetic microbiological safety. FDA has presented its preferred laboratory procedures for microbiological analyses of foods and cosmetics in its Bacteriological Analytical Manual (BAM). Chapter 23 of the BAM concerns microbiological methods for cosmetics (available at *http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/ucm073598.htm*).

Microbial contamination of cosmetic products is of concern to FDA because of the potential for serious adverse events. Cosmetics intended to be used in the area of the eye are of particular concern. Eye-area cosmetics that contain pathogenic microorganisms have the potential to cause serious eye infections which can, in some cases, result in partial or total loss of vision. In addition, contaminated alcohol-free mouthwash has caused outbreaks of serious bacterial illness among hospitalized patients. Other microbially contaminated cosmetic product types, such as skin lotions, also have the potential to cause significant irritation or infection.

A variety of factors can affect the microbiological safety of cosmetic products. Microbial contaminants can be introduced during manufacturing, packaging, or repacking. Microbial growth can be supported by certain product characteristics, such as high water content. Microorganisms can also be introduced by consumers during use. Certain forms of cosmetic product packaging may serve to limit or prevent the introduction of microorganisms. Preservative systems are intended to protect consumers from microorganisms introduced during manufacturing and while using a product, but inadequate preservative systems may fail to do so. Some microorganisms are known to be pathogenic, that is, they are capable of causing injury or illness, while others are not. Certain microorganisms may pose little risk to most consumers, but may pose significant risks to vulnerable consumers, such as those with compromised immune systems.

FDA believes that guidance on factors and practices to promote the microbiological safety of cosmetics would benefit consumers and industry. FDA is contemplating developing such guidance and is seeking information about microbiological safety of cosmetics. This public meeting is intended to provide stakeholders the opportunity to present information regarding microbiological testing of cosmetics; types of preservative systems and how to test their efficacy; the identity and prevalence of microorganisms, including antibiotic-resistant strains, that pose specific health risks in finished products; routes of exposure to microorganisms and the corresponding infective doses; product and packaging characteristics that affect microbial growth and risk of infection; particular subpopulations that may be at greater risk of infection when using different cosmetic products; the occurrence of adverse events associated with microbial contamination of cosmetics; and any other issues relevant to the microbiological safety of cosmetics.

II. Purpose and Format of the Meeting

If you wish to present at the meeting scheduled for November 30, 2011, please register at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm* by November 10, 2011. If you wish to attend the meeting but not give a presentation, please register at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm* by November 21, 2011. FDA is holding the public meeting on cosmetic microbiological safety issues to receive input from the public to support the development of guidance. The meeting format will include introductory presentations by FDA, followed by the opportunity for stakeholders to make presentations or offer remarks. Listening to our stakeholders is the primary purpose of this meeting. In order to meet this goal, FDA will provide multiple opportunities for individuals to actively express their views by making presentations at the meeting and submitting written comments to FDA's Division of Dockets Management within 60 days of this meeting.

III. How To Participate in the Meeting

Stakeholders will have an opportunity to provide oral comments. Due to limited space and time, FDA encourages all persons who wish to attend the meeting to register in advance. Interested persons and organizations who desire an opportunity to make an oral presentation during the time allotted for public comment at the meeting, are encouraged to register in advance and to provide the specific topic or issue to be addressed and the approximate desired length of their presentation. Depending on the number of requests for such oral presentations, there may be a need to limit the time of each oral presentation (*e.g.,* 3 minutes each). If time permits, individuals or organizations that did not register in advance may be granted the opportunity for such an oral presentation. FDA would like to maximize the number of stakeholders who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their views at the meeting. FDA encourages persons and groups who have similar interests to consolidate their information for presentation through a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the amount of time available and the approximate time their presentation is scheduled to begin. Stakeholders will also have an opportunity to submit electronic or written comments to the docket following the meeting, but no later than January 30, 2012.

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 because seating is limited.

Table 1 of this document provides information on participating in the meeting and on submitting comments to the docket.

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

	Date	Electronic address	Address (non-electronic)	Other information
Date of Public Meeting ..	November 30, 2011, from 9 a.m. to 5:30 p.m. EST.	Individuals who wish to participate in person are asked to pre-register at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	L'Enfant Plaza Hotel, 480 L'Enfant Plaza Southwest, Washington, DC, 20024–2253.	Registration begins at 8 a.m.
Advance Registration	Register by November 21, 2011.	*http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	FDA encourages the use of electronic registration if possible.	Registration to attend the meeting will also be accepted onsite on the day of the meeting, as space permits. Registration information may be posted without change to *http://www.regulations.gov* including any personal information provided.
Request special accommodations due to disability.	Register by November 21, 2011.	Juanita Yates, e-mail: *Juanita.Yates@fda.hhs.gov*.	Juanita Yates, 240–402–1731.	

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.

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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.