

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-2015-D-3056 for "Distributor Labeling for New Animal Drugs." 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 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 guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Dorothy McAdams, Center for Veterinary Medicine, Division of Surveillance (HFV-210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5763, email: [dorothy.mcadams@fda.hhs.gov](mailto:dorothy.mcadams@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of September 10, 2015 (80 FR 54568), FDA published the notice of availability for a draft guidance entitled "Distributor Labeling for New Animal Drugs" giving interested persons until November 9, 2015, to comment on the draft guidance. FDA received no comments on the draft guidance. The guidance announced in this notice finalizes the draft guidance dated September 2015.

##### II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on distributor labeling for new animal drugs. 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 guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 in 21 CFR 514.80 have been approved under OMB control number 0910-0284.

#### IV. Electronic Access

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

Dated: April 13, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-09141 Filed 4-19-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-1024]

#### Preparation for International Cooperation on Cosmetics Regulation

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

**ACTION:** Notice of meeting.

The Food and Drug Administration (FDA or we) is announcing a public meeting entitled "International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR-10 Meeting." The purpose of the meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the ICCR-10 meeting that will be held July 12-14, 2016, in Bethesda, MD.

*Date and Time:* The public meeting will be held on June 15, 2016, from 2 p.m. to 4 p.m.

*Location:* This meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Wiley Auditorium, College Park, MD 20740.

*Contact Person:* Maria Rossana (Rosemary) Cook, Office of Cosmetics and Colors, Food and Drug Administration, 4300 River Rd., College Park, MD 20740, [maria.cook@fda.hhs.gov](mailto:maria.cook@fda.hhs.gov), or FAX: 301-436-2975.

*Registration and Requests for Oral Presentations:* Send registration information (including your name, title, firm name, address, telephone number, fax number, and email address), written material, and requests to make an oral presentation, to the contact person by June 1, 2016.

If you need special accommodations due to a disability, please contact Maria Rossana (Rosemary) Cook at least 7 days in advance of the meeting.

**SUPPLEMENTARY INFORMATION:** You may present proposals for future ICCR agenda items, data, information, or views, orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes or less for each presenter. If you wish to make an oral presentation, you should notify the contact person by June 1, 2016, and submit a brief statement of the general nature of the evidence or arguments that you wish to present, your name, address, telephone number, fax number, and email address, and indicate the approximate amount of time you need to make your presentation.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20850. A transcript will also be available in either 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>.

*The Purpose of the Multilateral Framework on the ICCR:* The purpose of the multilateral framework on the ICCR is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection.

ICCR is a voluntary international group of cosmetics regulatory authorities from Brazil, Canada, the European Union, Japan, and the United States of America. These regulatory authority members will enter into constructive dialogue with their relevant cosmetics industry trade associations and public advocacy groups. Currently, the ICCR members are: The Brazilian Health Surveillance Agency; Health Canada; the European Commission Directorate-General for Internal Market, Industry, Entrepreneurship, and Small and Medium-sized Enterprises; the Ministry of Health, Labor, and Welfare of Japan; and FDA. All decisions made by

consensus will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will need input from stakeholders.

*Agenda:* We will make the agenda for the public meeting available on the Internet at <http://www.fda.gov/Cosmetics/InternationalActivities/ICCR/default.htm>. Depending on the number of requests for oral presentations, we intend to have an agenda available by June 8, 2016. We may use the information that you provide to us during the public meeting to help us prepare for the July 12–14, 2016, ICCR–10 meeting.

Dated: April 13, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–09143 Filed 4–19–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2013–N–0375]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Agreement for Shipment of Devices for Sterilization

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements relating to shipment of nonsterile devices that are to be sterilized elsewhere or are shipped to other establishments for further processing, labeling, or repacking.

**DATES:** Submit either electronic or written comments on the collection of information by June 20, 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”).

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- 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–2013–N–0375 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Agreement for Shipment of Devices for Sterilization.” 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