DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0830]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Abbreviated New Drug Applications and 505(b)(2) Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Abbreviated New Drug Applications and 505(b)(2) Applications'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On October 6, 2016, the Agency submitted a proposed collection of information entitled ''Abbreviated New Drug Applications and 505(b)(2) Applications'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0786. The approval expires on November 30, 2019. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: November 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–28655 Filed 11–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2153]

Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes.'' Flexible gastrointestinal endoscopes and accessories are class II devices and identified with product codes such as FDF, FDS, and OCX. When using these devices during an entire day of procedures (*e.g.,* colonoscopies), clinicians typically use one irrigation system (*i.e.,* one water bottle, one set of tubing and valves, etc.) without cleaning and sterilizing all the system components between patients. This guidance highlights the cross-contamination risk associated with day-use of irrigation systems used with flexible gastrointestinal endoscopes; clarifies terminology used to describe these devices; and outlines strategies to mitigate the risk of cross-contamination between patients during these procedures.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

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'').

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–2014–D–2153 for ''Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes.'' 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.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Shanil Haugen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G104, Silver Spring, MD 20993–0002, 301–796–0301.

SUPPLEMENTARY INFORMATION:

I. Background

Flexible gastrointestinal endoscopes and accessories (including valves and other devices used for irrigation) are class II devices regulated under 21 CFR 876.1500, *Endoscope and accessories.* During a colonoscopy or esophagogastroduodenoscopy (EGD), clinicians often use an irrigation system comprised of a water bottle, tubing, valves, etc., to supply irrigation for the procedure. Clinicians typically do not clean and sterilize all components of the irrigation system after each procedure; *e.g.,* they may use a single water bottle for an entire day of procedures without reprocessing the water bottle between patients. This practice raises the risk of cross-contamination between patients, because the water bottle and associated tubing and connectors can become contaminated with the fluids and materials (*e.g.,* blood, stool) of patients that travel back through the irrigation system channels and tubing during the procedure.

FDA is providing this guidance to highlight the cross-contamination risk posed by specific practices and types of irrigation valves and accessories; clarify terminology used to describe irrigation system components; and outline recommended mitigation strategies (*e.g.,* device design, labeling) meant to reduce the risk of cross-contamination between patients from the day-use of irrigation system tubing, valves, and accessories. FDA announced the availability of the draft guidance in the **Federal Register** of January 20, 2015 (80 FR 2711). Interested persons were invited to comment by April 20, 2015, and the final guidance includes revisions intended to address the comments received.

II. Significance of Guidance

This 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 Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes. 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. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400054 to identify the guidance you are requesting.

IV. 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 part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

Dated: *November 22, 2016.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–28604 Filed 11–28–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0735]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Superimposed Text in Direct-to-Consumer Promotion of Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 29, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW nd title Superimposed Text in Direct-to-Consumer Promotion of Prescription Drugs. Also include the FDA docket