

**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](mailto: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