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 0910–0539. The approval expires on August 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: October 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24444 Filed 10–14–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1414]

Agency Information Collection Activities; Proposed Collection; Comment Request; Class II Special Controls Guidance Document: Labeling of Natural Rubber Latex Condoms

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 the information collection for the labeling of natural rubber latex condoms.

DATES: Submit either electronic or written comments on the collection of information by December 15, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information 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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300—(OMB Control Number 0910–0633)—Extension

Under the Medical Device Amendments of 1976 (Pub. L. 94–295), class II devices were defined as those devices for which there was insufficient information to show that general controls themselves would provide a reasonable assurance of safety and effectiveness but for which there was sufficient information to establish performance standards to provide such assurance.

Condoms without spermicidal lubricant containing nonoxynol 9 are classified in class II. They were originally classified before the enactment of provisions of the Safe Medical Devices Act of 1990 (Pub. L. 101–629), which broadened the definition of class II devices and now permit FDA to establish special controls beyond performance standards, including guidance documents, to help provide reasonable assurance of the safety and effectiveness of such devices.

In December 2000 Congress enacted Public Law 106–554, which, among other provisions, directed FDA to ''reexamine existing condom labels'' and ''determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness in preventing sexually transmitted diseases * * *.'' In response, FDA recommended labeling intended to provide important information for condom users, including the extent of protection provided by condoms against various types of sexually transmitted diseases.

Respondents to this collection of information are manufacturers and repackagers of male condoms made of natural rubber latex without spermicidal lubricant. FDA expects approximately 5 new manufacturers or repackagers to enter the market yearly and to collectively have a third-party disclosure burden of 60 hours. The number of respondents cited in table 1 of this document is based on FDA's database of premarket submissions and the electronic registration and listing database. The average burden per disclosure was derived from a study performed for FDA by Eastern Research Group, Inc., an economic consulting firm, to estimate the impact of the 1999 over-the-counter (OTC) human drug labeling requirements final rule (64 FR 13254, March 17, 1999). Because the packaging requirements for condoms are similar to those of many OTC drugs, we believe the burden to design the labeling for OTC drugs is an appropriate proxy for the estimated burden to design condom labeling.

The special controls guidance document also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR 807 subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

The collection of information under § 801.437 does not constitute a ''collection of information'' under the PRA. Rather, it is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300	5	1	5	12	60

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

Dated: October 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24445 Filed 10–14–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0114]

Distinguishing Medical Device Recalls From Medical Device Enhancements; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled, ''Distinguishing Medical Device Recalls From Medical Device Enhancements.'' This guidance is intended to clarify when a potential change to a device is a medical device recall, distinguish those instances from product enhancements, and explain reporting requirements.

DATES: Submit either electronic or written comments on this guidance at any time.

ADDRESSES: 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 single copies of the guidance document entitled, ''Distinguishing Medical Device Recalls From Medical Device Enhancements'' 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.

Submit electronic comments on the guidance 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ronny Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2654, Silver Spring, MD 20993–0002, 301–796–6163.

I. Background

Defects or performance failures of marketed medical devices can pose serious risks to public health. The recall process serves both to correct the device defects and to notify users of potential risks and steps to minimize the impact of device failure or improper function. The recall process establishes a mechanism for firms that produce and market medical devices to take timely action to correct or remove violative devices.

When a firm's recall process is operating effectively, the firm identifies a device defect or failure, determines that a recall is appropriate, and triggers the initiation of the recall process. However, firms may have trouble identifying whether a change to a device meets the definition of a recall, the appropriate scope of a recall, and when FDA should be notified of a recall. These issues can result in delays in notifying the public about unsafe medical devices.

FDA also recognizes that continuous improvement activities, as part of an effective quality system, often have a favorable impact on medical device safety and are part of ongoing efforts to design and manufacture devices that meet the needs of the user and patient. When a new iteration of a device has improved design, for example, this does not necessarily mean that the prior version of the device should be recalled. Such changes may be appropriately characterized instead as product enhancements. In addition to determining whether a proposed change to a marketed device meets the definition of a device recall or a product enhancement, a firm must assess whether it is required to report the change to FDA.

In the **Federal Register** of February 22, 2013 (78 FR 12329), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by May 23, 2013. Multiple comments were received with recommendations pertaining to three main areas: (1) Clarification of definitions; (2) requests for more examples; and (3) clarification of reporting obligations pertaining to 21 CFR part 806. In response to these comments, FDA revised the guidance document to enhance clarity through the inclusion of multiple new examples. Some previously-included examples were deleted or reframed for improved clarity, and some content was removed since it did not enhance clarity and in some cases led to confusion. The guidance as revised provides more succinct information about the distinctions between medical device recalls and medical device enhancements and related reporting obligations. The guidance is organized in a question-and-answer format, providing responses to questions that FDA believes are helpful in properly identifying medical device recalls and applying reporting requirements.

II. Significance of Guidance

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the difference between a medical device recall and a