

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.

Biosimilars User Fee Cover Sheet; Form FDA 3792 (OMB Control Number 0910-0718)—Extension

The Patient Protection and Affordable Care Act (Pub. L. 111-148) contains a subtitle called the Biologics Price

Competition and Innovation Act of 2009 (Title VII Subtitle A) (BPCI Act) that amends the Public Health Service Act (42 U.S.C. 262) (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act, added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product. The BPCI Act also amends section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications in the definition of "human drug application" for the purposes of the prescription drug user fee provisions. The BPCI Act directs FDA to develop recommendations for a biosimilar biological product user fee program for fiscal years 2013 through 2017. FDA's recommendations for a biosimilar biological product user fee program were submitted to Congress on January 13, 2012.

FDA's biosimilar biological product user fee program requires FDA to assess and collect user fees for certain meetings concerning biosimilar

biological product development (BPD meetings), investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biological product applications and supplements. Form FDA 3792, the Biosimilars User Fee Cover Sheet, requests the minimum necessary information to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fees submitted for a submission with the actual submission by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs, applications, and supplements, and to account for and track user fees associated with BPD meetings.

Respondents to this collection of information are manufacturers of biosimilar biological product candidates. Based on the number of Form FDA 3792s we have received, we estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

| FDA form No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Biosimilars User Fee Cover Sheet; Form FDA 3792 .. | 20 | 1 | 20 | 0.50 (30 minutes) ... | 10 |

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

Dated: January 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1414]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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

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 February 26, 2015.

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0633. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 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 five 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 part 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 21 CFR 801.437 does not constitute a “collection of information” under the Paperwork Reduction Act of 1995. 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)).

In the **Federal Register** of October 15, 2014 (79 FR 61874), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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: January 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 038

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized

Consensus Standards). This publication, entitled “Modifications to the List of Recognized Standards, Recognition List Number: 038” (Recognition List Number: 038), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: An electronic copy of Recognition List Number: 038 is available on the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 038 modifications and other standards related information.

Submit written requests for a single copy of the document entitled “Modifications to the List of Recognized Standards, Recognition List Number: 038” to the Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149.

Submit electronic comments on this document 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: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3632, Silver Spring,