

The reconsideration and appeal requests are not addressed in the FD&C Act but are discussed in the draft guidance. We estimate that we will receive three requests for reconsideration annually, and that the total average burden hours for a reconsideration request will be 24 hours. We estimate that we will receive one request annually for an appeal of a user fee waiver determination, and that the time needed to prepare an appeal would be approximately 12 hours. Reconsideration requests are sent to the Associate Director for Policy at the Center for Drug Evaluation and Research (CDER), and requests for appeals are sent to the User Fee Appeals Officer at FDA, with a copy to the Associate Director for Policy at CDER. We have also included in this estimate both the time needed to prepare the request for

appeal and the time needed to create and send a copy of the request for an appeal to the Associate Director for Policy at CDER.

The burden for filling out and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) has not been included in the burden analysis because that information collection is already approved by OMB under OMB control number 0910-0297. The collections of information associated with a new drug application or biologics license application have been approved under OMB control numbers 0910-0001 and 0910-0338, respectively.

We have included in the burden estimate the preparation and submission of application fee waivers for small businesses because small businesses requesting a waiver must submit

documentation to FDA on the number of their employees and must include the information that the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval. Because the Small Business Administration (SBA) makes the size determinations for FDA, small businesses must also submit information to the SBA. The submission of information to SBA is already approved by OMB under OMB control number 3245-0101.

In the **Federal Register** of March 14, 2011 (76 FR 13629), 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 REPORTING BURDEN <sup>1</sup>

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Section 736 of the FD&C Act .....	75	1.2	90	16	1,440
Reconsideration Requests .....	3	1	3	24	72
Appeal Requests .....	1	1	1	12	12
Total .....	.....	.....	.....	.....	1,524

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

Dated: July 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0595]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exports: Notification and Recordkeeping Requirements

**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 August 8, 2011.

**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 e-mailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0482. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794; *Jonna.Capezzuto@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:.

#### Exports: Notification and Recordkeeping Requirements—21 CFR Part 1 (OMB Control Number 0910-0482—Extension

The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or marketed in the United States as allowed under section 801(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act (21 U.S.C. 381)). In general, the notification identifies the product being exported (e.g. name, description, and in some cases, country of destination) and specifies where the notification should be sent. These notifications are sent only for an initial export; subsequent exports of the same product to the same destination (or, in the case of certain countries identified in section 802(b) of the FD&C Act (21 U.S.C. 382) would not result in a notification to FDA.

The recordkeepers to this information collection are exporters who export human drugs, biologics, devices, animal drugs, foods and cosmetics that may not be sold in the United States and maintain records demonstrating their

compliance with the requirements in section 801(e)(1) of the FD&C Act.

In the **Federal Register** of December 6, 2010 (75 FR 75677), 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 REPORTING BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
1.101 (d) .....	400	3	1,200	15	18,000

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR section	Number of record-keepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours
1.101(b), (c), (e) .....	320	3	960	22	21,120

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

Dated: July 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0492]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Class II Special Controls Guidance Document: Labeling for 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 information collection requirements for the labeling of natural rubber latex condoms.

**DATES:** Submit either electronic or written comments on the collection of information by September 6, 2011.

**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:

Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@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) that broadened the definition of class II devices and now permit FDA to establish special controls beyond performance standards, including guidance documents, to help provide