

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbio *ac*

[Docket No. FDA-2004-D-0375] (formerly Docket No. 2004D-0555)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry and Food and Drug Administration Staff; "Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300"

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 (the PRA).

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

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: 202-395-6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-NEW and title "Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300." Also include the FDA docket number found in brackets in the heading of this document.

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FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3793.

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-NEW)

Under the Medical Device Amendments of 1976 (Public Law 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 (Public Law 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 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* * *.” FDA is recommending labeling changes 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 believes that this is a one-time burden, because once a label is redesigned, it can be used indefinitely.

In the **Federal Register** of November 14, 2005 (70 FR 69156), FDA published a 60-day notice soliciting public comment on the information collection provisions, contained in the draft special controls guidance document then entitled "Labeling for Male Condoms Made of Natural Rubber Latex." FDA has subsequently retitled the special controls guidance document containing these information collection provisions to avoid confusion between the guidance established as a special control for condoms classified under 21 CFR 884.5300 by the final rule published elsewhere in this issue of the **Federal Register** and the November 2005 draft guidance, which remains available (but not for implementation) in conjunction with the pending proposal to amend another classification. No comments were received on the information collection provisions in response to the 60-day notice.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
35 ²	34	1,190	12	14,280
3 ³	34	102	12	1,224
Total				15,504

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

² Current manufacturers for year one.

³ New Manufacturers for years two and three.

The reporting burden hours to respondents in the first year is a one-time burden of 14,280 hours. FDA expects three new manufacturers or repackagers to enter the market yearly, and collectively have a one-time burden of 1,224

hours. The number of respondents and prospective new manufacturers cited in table 1 of this document are based on FDA's database of premarket submissions. The remaining figures were 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 redesign the labeling for OTC drugs is an appropriate proxy for the estimated burden to redesign condom labeling. Cost estimates were adjusted to account for inflation using the producer price index.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information under 21 CFR part 807 subpart E have been approved under OMB control no. 0910-0120; the collections of information under 21 CFR part 820 have been approved under OMB control no. 0910-0073; and the collections of information in part 801 (21 CFR part 801) have been approved under OMB control no. 0910-0485.

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)).

Dated: 10/30/08
October 30, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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