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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00N-1328]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Extension; Latex Condoms; User Labeling; Expiration Dating**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for an expiration date on latex condom labeling based on physical and mechanical testing performed after exposing the product to varying conditions that age latex.

**DATES:** Submit written comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (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:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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: (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.

**Latex Condoms; User Labeling; Expiration Dating—21 CFR 801.435 (OMB Control No. 0910–0352)—Extension**

Sections 502(a), 519, 701, and 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(a), 360(i), 371, and 374) establish the statutory authority to collect information under this regulation. Section 519 of the act describes recordkeeping, section 502(a) misbranding, section 704 authority for inspections, and section 701 general administrative procedures and regulations and hearings.

To protect the public health and minimize the risk of device failure, latex condoms are required to be labeled with an expiration date, which must be supported by data from quality control tests demonstrating physical and mechanical integrity of three random lots of the same product that were stored under accelerated and real time conditions (§ 801.435 (21 CFR 801.435)).

The recording of shelf life testing by condom manufacturers is used to support the expiration dating on the labeling of latex condoms. Information concerning latex shelf life is necessary to allow lay users to use these products safely by avoiding use of products that may have degraded. Degradation of latex film products like latex condoms occurs when latex is exposed to various types of environmental conditions normally experienced in product use, shipment, or storage situations. The effectiveness of latex condoms as a barrier to the transmission of infectious agents is dependent upon the integrity of the latex material. The information and records generated by condom manufacturers under this regulation will be used to establish an expiration date that will inform consumers when the product should no longer be used.

Section 510(h) of the act (21 U.S.C. 360(h)) requires that condom manufacturers as device manufacturers be inspected at least once in a 2-year period. During that inspection, FDA inspectors will review the test records used to support the expiration date in order to ensure that the expiration date is accurate.

The respondents to this collection of information are domestic and foreign condom manufacturers:

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

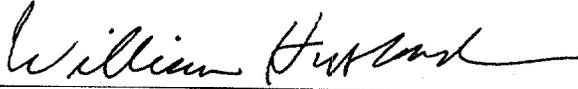
| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 801.435        | 45                 | 1                             | 45                     | 96                 | 4,320       |

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

The number of domestic establishments was estimated by reviewing the FDA data base of registered medical device manufacturers to arrive at 5 domestic and 40 foreign condom manufacturers. Based upon conversations with condom manufacturers, FDA field personnel, and

comments received from the public during this collections initial approval, FDA determined the number hours to complete labeling and testing of condoms to be 96 hours per respondent.

Dated: June 15, 2000



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William K. Hubbard,  
Senior Associate Commissioner  
for Policy, Planning, and Legislation.

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