

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1328]

DMB

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Certifier	J. W. Wicks

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Latex Condoms; User Labeling; Expiration Dating

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

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

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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) describes misbranding, section 704 describes authority for inspections, and section 701 describes 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.

In the **Federal Register** of June 23, 2000 (65 FR 39150), the agency requested comments 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 BURDEN¹

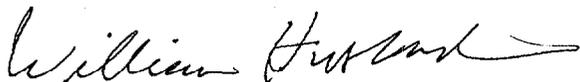
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.435	45	1	45	96	4,320

¹ 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: September 19, 2000



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

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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