accounts'' raise any issues peculiar to bank Trust Departments. The OCC and FRB proposals do not specifically address the ''sweep account'' issues identified herein.

Reporting of Personal Trading

Part 344 currently requires certain bank officers and bank employees engaged in or aware of the investment decisions or recommendations for customer accounts to provide quarterly reports regarding their personal trading of securities. Section 344.6(d). The regulation does not require reporting of personal trading where the securities transactions aggregate $10,000 or less during the calendar quarter. The SEC has a similar reporting requirement for principal underwriters and investment advisers of registered investment companies under the Investment Company Act of 1940. See SEC Rule 17j–1, 12 CFR 270.17j–1. The SEC Rule does not provide an exemption for securities transactions involving in the aggregate $10,000 or less. The FDIC requests comments on whether the exemption from reporting personal trading by bank officers and employees engaged in or aware of the investment decisions or recommendations for customer accounts in section 344.6(d) is appropriate. Additionally, the FDIC requests comment on whether all bank directors, as opposed to just those bank directors who are also officers or employees of the bank, should be required to report on their personal trading. The OCC and FRB proposals do not address the personal trading issues raised herein.

Additional Comment

The FDIC is interested in receiving any additional comments regarding part 344 which the public feels should be taken into account as the agency undertakes to modernize the regulation.

By Order of the Board of Directors.

Dated at Washington, DC, this 14th day of May, 1996.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 96–12928 Filed 5–23–96; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 95N–0374]

RIN 0910–AA32

Latex Condoms; User Labeling; Expiration Dating

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed regulation that would require the labeling of latex condoms to contain an expiration date based upon physical and mechanical testing performed after exposing the product to varying conditions that age latex. Studies show that latex condoms degrade over time. Such degradation has a significant effect on the product's ability to provide a barrier to sexually transmitted disease (STD) agents, including the human immunodeficiency virus (HIV). This requirement is being proposed in order to provide consumers with essential information regarding the safe use of these products.

DATES: Written comments on this proposed rule by August 22, 1996. Written comments on the information collection requirements should be submitted by June 24, 1996. FDA proposes that any final rule that may be issue based on this proposal become effective 180 days after the date of its publication in the Federal Register.

ADDRESSES: Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Donald E. Marlowe, Center for Devices and Radiological Health (HFZ–150), Food and Drug Administration, 12200 Wilkins Ave., Rockville, MD 20852, 301–443–7003.

SUPPLEMENTARY INFORMATION:

I. Background

It is estimated that over 1 million persons in the United States are infected with HIV (Ref. 1). HIV is transmitted primarily through sexual contact; however, nonsexual transmission has occurred in health care settings as a result of contact with infected blood. Additionally, HIV has been isolated from other body fluids in addition to blood. With the prevalence of HIV infection and the risk of transmission of other infections, the importance of the quality of an effective barrier to the transmission of infection is crucial.

Numerous studies in the scientific literature, including the proceedings of a conference on ''Latex as a Barrier Material'' sponsored by FDA in 1989, have addressed and overwhelmingly supported the use of latex membranes, such as condoms and medical gloves, as effective barriers against the transmission of various disease agents, including hepatitis, HIV, and other infections (Ref. 2). The Centers for Disease Control and Prevention (CDC) and the Surgeon General of the Public Health Service have recommended, on the basis of evidence that latex provides a barrier against the transmission of STD's, that latex condoms should be used according to instructions with every act of intercourse for maximum protection against STD's (Ref. 3). Two recent studies involving serodiscordant heterosexual couples (i.e., one partner is HIV positive, the other HIV negative) indicate that using latex condoms substantially reduces the risk of HIV transmission (Refs. 4 and 5). In one study, none of the 123 partners who used condoms consistently became infected while 12 (10 percent) of 122 partners who used condoms inconsistently became infected (Ref. 4). In the second study, 3 (2 percent) of the 171 consistent condom users became infected compared to 8 (15 percent) of 55 inconsistent condom users (Ref. 5).

The effectiveness of latex condoms as a barrier, however, is dependent upon the integrity of the latex material. Degradation of latex film products (e.g., the embrittlement of the latex film, an increase in the porosity of the membrane, or other loss of physical properties) occurs when latex is exposed to various types of environmental conditions (such as elevated temperature, fluorescent lights, or ozone) normally experienced in product use, shipment, or storage situations. Exposure to these environmental conditions degrades the film progressively over time, and may result in bursts, rips, tears or seepage that allows the transmission of infectious agents.

To understand the effects of aging and other storage conditions on latex properties, the State of Washington's Board of Pharmacy initiated an FDA-sponsored study of the material integrity

of latex condoms (the FDA/Washington study) in July 1989 (Ref. 6). This study was designed to investigate the effects of aging on latex condoms by studying burst pressure, burst volume, tensile strength, and elongation at breakage, after storage over different periods of time at varying temperatures. The study examined dry (nonlubricated) condoms and various types of lubricated condoms, produced by the major domestic condom manufacturers. The study consisted of two parts--laboratory testing, which ran for 3 years, and field testing, which is an ongoing study of normal condom aging at eight sites representing varying temperatures, elevations, and humidity conditions.

At the laboratories of the FDA/Washington study, packaged and unpackaged latex condoms were exposed to temperatures of 20 and 30 °C (representing room temperature) for up to 5 years. In order to represent exposure to the upper extreme of environmental temperatures, condoms were exposed for 100 days to a temperature of 45 °C. Also, to accelerate the aging process of the latex, condoms were exposed to temperatures of 70 and 85 °C for up to 100 days (Refs. 7 through 9). The study revealed that exposed condoms (i.e., condoms not protected by packaging) degraded to the point of being unusable within 1 year at room temperature, and at higher temperatures in as little as 10 days. The FDA/Washington study further shows that latex condoms stored in intact plastic packages also degrade over time, though at a much slower rate. The results of the FDA/Washington study demonstrate that aging and other conditions can significantly affect the integrity, strength, and quality of latex essential to maintaining a barrier against the transmission of disease.

At a meeting with the agency, condom manufacturers and FDA agreed that, based upon the American Society for Testing and Materials (ASTM) standards and the FDA/Washington study, two accelerated aging test conditions (i.e., storage for 7 days at 70 °C and storage for 90 days at 40 to 50 °C) properly evaluate aging properties of latex films. Given the evidence that aging affects the latex barrier properties of condoms that prevent the transmission of infectious agents, the agency believes latex condoms should not be used after aging has compromised latex barrier properties. Accordingly, FDA believes that such products should bear expiration dates, based upon appropriate testing, that will inform the user when these products should no longer be used. FDA is therefore proposing that latex condoms bear expiration dates.

Proposed § 801.435(c) would require an expiration date to appear on the primary packaging (i.e., the individual package), as well as higher levels of labeling, such as the case containing individually packaged products to ensure visibility.

To establish the expiration date, FDA is proposing to require manufacturers to subject their products to certain aging condition environments prior to conducting physical and mechanical testing that will demonstrate the product will maintain its barrier properties during the labeled shelf life of the product. The accelerated aging conditions would be based on data and test protocols proposed by the industry, and supported by existing condom standards (Ref. 10), and the findings of the Mandel and FDA/Washington studies (Refs. 7 and 6).

Specifically, FDA in proposed § 801.435(d) would require that a manufacturer, before performing tests on products that demonstrate physical and mechanical integrity of the product, subject products from three discrete and random lots to each of the following conditions: (1) Storage unpackaged for the maximum amount of time the manufacturer allows the product to remain unpackaged after manufacture, followed by storage of the packaged product at 70 °C (plus or minus 2 °C) for 7 days; (2) storage unpackaged for the maximum amount of time the manufacturer allows the product to remain unpackaged after manufacture, followed by storage of the packaged product at 40 to 50 °C (plus or minus 2 °C) for 90 days; and (3) storage unpackaged for the maximum amount of time the manufacturer allows the product to remain unpackaged after manufacture, followed by storage of the packaged product at 15 to 30 °C for the stated shelf life of the product.

Under proposed § 801.435(e), if the latex barrier properties are adequate (i.e., pass the manufacturer's reasonable physical and mechanical integrity tests) after undergoing the 70 °C /7-day and 40 to 50 °C/90-day tests, the product may be labeled with an expiration date of up to 5 years. If the product, after storage at either 7- or 90-day test conditions, fails to meet the manufacturer's physical or mechanical integrity tests, the labeled shelf life of the product would be required to be demonstrated by real-time storage data at 15 to 30 °C. Products that pass the 7- and 90-day test conditions, would be required to undergo confirmation tests after the product has been stored at 15 to 30 °C for the stated shelf life. If the product fails the 15 to 30 °C confirmation test, the product would be required to be relabeled to represent the actual shelf life supported by real time data.

Although FDA would not require manufacturers of currently marketed products to submit new 510(k) submissions prior to marketing condoms with expiration dates, all testing data must be retained in each company's files as required by 21 CFR 820.180, and remain available for FDA inspection. New 510(k) submissions should include data to establish labeled expiration dates.

The agency believes that the proposed 180-day time period between the publication date of the final rule and the effective date of the final rule would be sufficient time to conduct the required tests and ensure that all latex condoms being initially introduced into interstate commerce will bear an expiration date. Latex condoms introduced into interstate commerce after the effective date of a final rule based on this proposal, which do not bear appropriate expiration dates would be considered to be misbranded under sections 201(n), 502(a) and (f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(n), 352(a) and (f)(1)) in that their labeling fails to contain facts material to the consequences of their use, and fails to bear adequate directions for use.

II. Statement of Law

Section 701(a) of the act (21 U.S.C. 371(a)) authorizes FDA to issue substantive binding regulations for the efficient enforcement of the act. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); see also *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973); *National Ass'n of Pharmaceutical Manufacturers* v. *FDA*, 637 F.2d 877 (2d Cir. 1981); *National Confectioners Ass'n* v. *Califano*, 569 F.2d 690 (D.C. Cir 1978); *National Nutritional Foods Ass'n* v. *Weinberger*, 512 F.2d 688 (2d Cir.) *cert. denied*, 423 U.S. 825 (1975).

Under the proposed rule, any latex condom that is not labeled as required and that is introduced or delivered for introduction into commerce after the effective date of a final rule would be misbranded under sections 201(n) and 502(a) and (f)(1) of the act (21 U.S.C. 321(n) and 352(a) and (f)(1)). Section 502(a) of the act provides that a device is misbranded if ''its labeling is false or misleading in any particular.'' Section 201(n) of the act provides that, in determining whether labeling of a regulated article (such as a device) is misleading:

* * * there shall be taken into account * * * not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling * * * fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling * * * relates * * *.

The shelf life of latex condoms is material information that consumers need in order to safely use latex products. The omission of shelf life would constitute an omission of a material fact and would render latex condoms without an expiration date misbranded within the meaning of section 502(a) of the act. The courts have upheld FDA's authority to prevent false and misleading labeling by promulgating regulations requiring label warnings and other affirmative disclosures, see, e.g., *Cosmetic, Toiletry and Fragrance Association* v. *Schmidt*, 409 F. Supp. 57 (D.D.C. 1976), *aff'd without opinion*, Civil No. 75–1715 (D.C. Cir. August 19, 1977), even in the absence of a proven cause and effect relationship between product usage and harm, *Council for Responsible Nutrition* v. *Goyan*, Civil No. 80–1124 (D.D.C. August 1, 1980).

Section 502(f)(1) of the act provides that a device is also misbranded unless its labeling bears adequate directions for use. Adequate directions for use means adequate directions under which a layperson can use a device safely and for the purpose for which it is intended (see 21 CFR 801.4 and 801.5). Information concerning latex condom shelf life is necessary to allow lay users to use these products safely by avoiding use of products that may have degraded. Failure to include such information would render the products misbranded under section 502(f)(1) of the act.

FDA may impose testing requirements in a labeling regulation issued under its general rulemaking authority. See, e.g., *American Frozen Food Inst.* v. *Mathews*, 413 F. Supp. 548 (D.D.C. 1976), *aff'd per curiam sub nom. American Frozen Food Inst.* v. *Califano*, 555 F.2d 1059 (D.C. Cir 1977); see also *National Nutritional Foods Ass'n* v. *Weinberger*, supra. Thus, FDA may require that all latex condom manufacturers use the same conditions to test aging to ensure that the expiration date reflects the period of time a product can be used safely. A similar requirement is imposed in 21 CFR 801.430(f) for absorbency tests for menstrual tampons, and in 21 CFR 801.420(c)(4) on hearing aid manufacturers and distributors who must determine and state technical data values for hearing aid labeling in accordance with specified test procedures. The hearing aid regulation has been upheld. *American Speech and Hearing Ass'n* v. *Califano*, Medical Devices Report (CCH) No. 77–1327 §§ 15004, 15007 (D.D.C. August 23, 1977), *aff'd* No. 77–1327 (D.C. Cir. Dec. 19, 1977). Food regulations issued under section 701(a) of the act also impose many such specific testing requirements (see, e.g., 21 CFR 113.40 (tests for low-acid canned foods); 21 CFR 155.190(b)(2)(i) (test for determining drained weight of canned tomatoes); 21 CFR 161.190 (method for determining color designation of tuna)).

Consumers must be aware of the potential for degradation of latex condoms in order to safely use such products to provide a barrier from infectious agents. Accordingly, FDA believes that the shelf life is a material fact to the consequences of use of latex condoms. FDA also believes that a shelf life is necessary to provide the consumer with adequate directions for use. After the effective date of the final regulation, FDA will consider latex condoms that do not provide this information to be misbranded under sections 201(n), 502(a) and (f)(1) of the act because they fail to contain facts material to the consequences of their use, and fail to bear adequate directions for use.

III. Preemption

FDA advises that any labeling requirement based upon this proposal would, under section 521(a) of the act (21 U.S.C. 360k(a)), preempt any State or local requirement that is different from, or in addition to, FDA's labeling requirement. Section 521(a) of the act provides that no State or local government may establish any requirement applicable under the act if such requirement is different from, or in addition to, a requirement which is applicable to the device under the act.

In 1991, the State of Washington requested an advisory opinion regarding the preemption of its State requirement that condom labels bear a 3-year expiration date. One condom manufacturer had objected to the State law, on the grounds that its 510(k) clearance included labeling for a 5-year shelf life. The agency determined that the State requirement was not preempted by section 521(a) of the act because, at that time, there was no counterpart Federal requirement with respect to expiration date labeling for condoms. FDA's ''General Guidance for Modifying Condom Labeling to Include Shelf Life'' (Ref. 11) provided premarket notification procedures for manufacturers who choose voluntarily to affix shelf life dates to their condom packages. That document did not establish a ''requirement'' within the meaning of section 521(a) of the act. This proposed rule, when final, however, would constitute a requirement which will preempt any State or local requirement regarding the expiration date labeling of latex condoms which is different from, or in addition to, the final regulation.

IV. Labeling For Other Latex-Film Products

The agency recognizes that the unique packaging of latex condoms (i.e., product sealed individually in air-tight packages) makes it difficult to extrapolate the data relating to latex condoms to other latex-film medical devices that have packaging which may provide a different level of protection from environmental conditions. Given the evidence that aging affects the integrity of latex films, FDA believes that medical devices containing or composed of a latex film should provide information regarding the age of the latex film. In order to address this issue, FDA is initiating a study to determine at what rate latex gloves degrade under various environmental conditions.

Until the agency compiles sufficient data to propose an expiration date for latex devices other than condoms, the agency is considering whether to require devices containing or consisting of latex films, other than latex condoms, to be labeled with the date of manufacture (i.e., the date the latex film was formed by dipping). Although the date of manufacture provides no information about the expected life of the product, it will provide age information. Based upon such age information, consumers may make a more informed choice regarding the use of the product.

Furthermore, as shown in the FDA/Washington study cited above, latex films are far more stable in intact packages than when exposed. Because the normal use of some products (such as nonsterile examination gloves, sold in dispenser boxes of 100), includes storage in opened packages, FDA is also considering additional labeling information requirements for products normally dispensed in open containers, including the statement ''Heat and light accelerate the degradation of latex films. Store opened containers away from heat and light.''

FDA invites advance comments on these issues. Meanwhile, FDA encourages manufacturers to voluntarily provide information to consumers regarding the age of latex film devices, and additional educational materials and ancillary information regarding the

stability and best storage conditions of such products, as appropriate.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposed regulation would require physical and mechanical integrity tests. Because condom manufacturers routinely conduct such tests on their products, the required testing would affect manufacturers only by establishing storage conditions prior to testing such products. This proposed rule would also require a labeling change. The proposed 180-day time period between the publication date and effective date of the final rule based upon this proposal would allow most manufacturers to exhaust their existing supply of labels. Accordingly, for the above-stated reasons, the agency certifies that the proposed rule will not have a significant economic impact on small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for 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.

Title: Labeling Requirements for Latex Condoms—Expiration Date Labeling.

Description: These information collection requirements apply to condom manufacturers. This proposed rule expands the labeling of latex condoms to contain an expiration date. The expiration date must be supported by data from quality control tests demonstrating physical and mechanical integrity of three random lots of the same product which were stored under accelerated and real time conditions. Quality control testing under accelerated conditions must include tests of: (1) Unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged; (2) packaged product stored at a specified temperature for 7 days; and (3) packaged product stored at a specified temperature for 90 days. Quality control testing must also be done under real time conditions, i.e., on packaged product at a specified temperature for the entire expiration period (up to 5 years).

The recording of shelf life testing by condom manufacturers is used to support the inclusion of expiration dating on the labeling of latex condoms. Information concerning latex condom shelf life is necessary to allow lay users to use these products safely by avoiding use of products that may have degraded. The effectiveness of latex condoms as a barrier to the transmission of infectious agents is dependent upon the integrity of the latex material. The shelf life of latex condoms is material information that consumers need in order to safely use latex products.

Condom manufacturers will use the information collected from the testing to establish the expiration date to be printed on the labeling and purchasers will use the information collected to determine likely effectiveness.

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.

Description of Respondents: Businesses or other for profit organizations.

Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
801.435(d)	58	1	58	120[1]	6,960[1]	$9,280[2]	$125,280[1]

[1] The annual burden reported here represents a year in which a manufacturer would have conducted testing at 0 days, 7 days, 90 days, and 5 years (in support of a labeled expiration period of 5 years). However, FDA expects that testing at 0 days, 7 days, and 90 days would be conducted during 1 year to justify a 5-year expiration period, and that testing on 5-year-old product would be conducted in another year.

[2] Capital costs are one time start-up costs and consist of a revision of policies and procedures.

As required by section 3507(d) of the Paperwork Reduction Act of 1995, FDA has submitted the collections of information contained in the proposed rule to OMB for review. Other organizations and individuals should submit comments on the information collection requirements by June 24, 1996, and should direct them to the

Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

VIII. Comments

Interested persons may, on or before August 22, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Center for Disease Control and Prevention, ''HIV Prevalence Estimates and AIDS Case Projections for The United States: Report Based Upon a Workshop,'' *Morbidity and Mortality Weekly Report*, vol. 39/No. RR–16, November 30, 1990.

2. Conference on Latex as a Barrier Material, University of Maryland, (sponsored by FDA), May 1989.

3. Center for Disease Control, ''Update: Barrier Protection Against HIV Infection and Other Sexually Transmitted Diseases,'' *Morbidity and Mortality Weekly Report*, vol. 42/No. 30, August 6, 1993.

4. DeVincenzi, L., European Study Group on Heterosexual Transmission of HIV, Heterosexual Transmission of HIV in a European Cohort of Couples (abstract No. WSCO2–1), vol.1, IXth International Conference on AIDS/HIV STD World Congress. Berlin, 83, June 9, 1993.

5. Saracco, A., M. Musicco, A. Nicolosi, et al., ''Man-to-Woman Sexual Transmission of HIV: Longitudinal Study of 343 Steady Partners of Infected Men,'' *Journal of Acquired Immune Deficiency Syndrome*, 6:497–502, 1993.

6. Final Report: Lubricated Latex Condoms—Study of the Effects of Environmental Parameters on Deterioration: Program for Appropriate Technology in Health (PATH), FDA Contract No. 223–88–4285, October 1993.

7. Mandel, J. et al., ''Measurement of the Aging of Rubber Vulcanizates'' *Journal of Research of the National Bureau of Standards*, vol. 63C, No. 2, October-December, 1959.

8. Barker, L. R., Accelerated and Long-Term Ageing of Natural Rubber Vulcanisates: *Journal of Natural Rubber Research*, vol. 2, No. 4, pp. 201–213 (1987).

9. Barker, L. R., Accelerated Long-Term Ageing of Natural Rubber Vulcanisates, Part 2: Results From Ageing Tests at 40 C, *Journal of Natural Rubber Research*, vol. 5, No. 3, pp. 266–274, 1990.

10. ASTM D 3492, Standard Specification for Rubber Contraceptives (Condoms), American Society for Testing and Materials, Philadelphia, PA.

11. ''General Guidance for Modifying Condom Labeling to Include Shelf Life,'' Division of Small Manufacturers Assistance, Center for Devices and Radiological Health, Rockville, MD.

List of Subjects in 21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 801 be amended as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

2. New § 801.435 is added to subpart H to read as follows:

§ 801.435 User labeling for latex condoms.

(a) This section applies to the subset of condoms as identified in § 884.5300 of this chapter, and condoms with spermicidal lubricant as identified in § 884.5310, which products are formed from latex films.

(b) Data show that the material integrity of latex condoms degrades over time. To protect the public health and minimize the risk of device failure, latex condoms must bear an expiration date which is supported by testing as described in paragraph (d) of this section.

(c) The expiration date, as demonstrated by testing procedures described in paragraph (d) of this section, must be displayed prominently and legibly on the primary packaging (e.g., individual package), and higher levels of packaging (e.g., boxes of condoms), in order to ensure visibility of the expiration date.

(d) The expiration date must be supported by data from reasonable quality control tests demonstrating the physical and mechanical integrity of the product after three discrete and random lots of the same product have been subjected to each of the following conditions:

(1) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at 70 °C (plus or minus 2 °C) for 7 days;

(2) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a selected temperature between 40 and 50 °C (plus or minus 2 °C) for 90 days; and

(3) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a monitored or controlled temperature between 15 and 30 °C for the lifetime of the product (real-time storage).

(e) If a product fails the manufacturer's reasonable quality control tests for physical and mechanical integrity after the completion of the accelerated storage tests described in paragraphs (d)(1) and (d)(2) of this section, the product expiration date must be demonstrated by real-time storage conditions described in paragraph (d)(3) of this section. If all of the products tested after storage at temperatures as described in paragraphs (d)(1) and (d)(2) of this section pass the manufacturer's reasonable physical and mechanical integrity tests, the manufacturer may label the product with an expiration date of up to 5 years from the date of product packaging. If the extrapolated expiration date, under paragraphs (d)(1) and (d)(2) of this section, is used, the labeled expiration date must be confirmed by reasonable physical and mechanical integrity tests performed at the end of the stated expiration period as described in paragraph (d)(3) of this section. If the data from tests following real-time storage described in paragraph (d)(3) of this section fails to confirm the extrapolated expiration date, the manufacturer must, at that time, relabel the product to reflect the actual shelf life.

(f) The time period upon which the expiration date is based shall start with the date of packaging.

(g) All testing data must be retained in each company's files, as required by § 820.180 of this chapter, and shall be made available, upon request, for inspection by FDA.

(h) Any latex condom not labeled with an expiration date as required by paragraph (c) of this section, and delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a) and (f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n), 352(a) and (f)).

Dated: May 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–13174 Filed 5–23–96; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[AD–FL–5510–2]

Clean Air Act Interim Approval of Operating Permits Program; Delegation of Section 112 Standards; State of Vermont

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes interim approval of the Operating Permits Program submitted by Vermont for the purpose of complying with Federal requirements for an approvable State program to issue operating permits to all major stationary sources, and to certain other sources. EPA is also approving Vermont's authority to implement hazardous air pollutant requirements.

DATES: Comments on this proposed action must be received in writing by June 24, 1996.

ADDRESSES: Comments should be addressed to Donald Dahl, Air Permits, CAP, U.S. Environmental Protection Agency, Region I, JFK Federal Building, Boston, MA 02203–2211. Copies of the State's submittal and other supporting information used in developing the proposed interim approval are available for inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region 1, One Congress Street, 11th floor, Boston, MA 02203–2211.

FOR FURTHER INFORMATION CONTACT: Donald Dahl, CAP, U.S. Environmental Protection Agency, Region 1, JFK Federal Building, Boston, MA 02203–2211, (617) 565–4298.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

A. Introduction

As required under title V of the 1990 Clean Air Act Amendments (sections 501–507 of the Clean Air Act (''the Act'')), EPA has promulgated rules which define the minimum elements of an approvable State operating permits program and the corresponding standards and procedures by which the EPA will approve, oversee, and withdraw approval of State operating permits programs (see 57 FR 32250 (July 21, 1992)). These rules are codified at 40 Code of Federal Regulations (CFR) Part 70. Title V requires States to develop, and submit to EPA, programs for issuing these operating permits to all major stationary sources and to certain other sources.

The Act requires that States develop and submit these programs to EPA by November 15, 1993, and that EPA act to approve or disapprove each program within 1 year after receiving the submittal. The EPA's program review occurs pursuant to section 502 of the Act and the part 70 regulations, which together outline criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of Part 70, EPA may grant the program interim approval for a period of up to 2 years. If EPA has not fully approved a program by 2 years after the November 15, 1993 date, or by the end of an interim program, it must establish and implement a Federal program.

B. Federal Oversight and Sanctions

If EPA were to finalize this proposed interim approval, it would extend for two years following the effective date of final interim approval, and could not be renewed. During the interim approval period, the State of Vermont would be protected from sanctions, and EPA would not be obligated to promulgate, administer and enforce a Federal permits program for the State of Vermont. Permits issued under a program with interim approval have full standing with respect to part 70, and the 1-year time period for submittal of permit applications by subject sources begins upon the effective date of interim approval, as does the 3-year time period for processing the initial permit applications [1].

Following final interim approval, if the State of Vermont failed to submit a complete corrective program for full approval by the date 6 months before expiration of the interim approval, EPA would start an 18-month clock for mandatory sanctions. If the State of Vermont then failed to submit a corrective program that EPA found complete before the expiration of that 18-month period, EPA would apply sanctions as required by section 502(d)(2) of the Act, which would remain in effect until EPA determined that the State of Vermont had corrected the deficiency by submitting a complete corrective program. If, six months after application of the first sanction, the State of Vermont still has not submitted a corrective program that EPA finds complete, a second sanction will be required.

If, following final interim approval, EPA were to disapprove the State of Vermont's complete corrective program, EPA would be required under section 502(d)(2) to apply sanctions on the date 18 months after the effective date of the disapproval, unless prior to that date the State of Vermont had submitted a revised program and EPA had determined that it corrected the deficiencies that prompted the disapproval. If, six months after EPA applies the first sanction, the State of Vermont has not submitted a revised program that EPA has determined corrected the deficiencies that prompted disapproval, a second sanction will be required.

Moreover, if EPA has not granted full approval to the State of Vermont's program by the expiration of an interim approval and that expiration occurs after November 15, 1995, EPA must promulgate, administer and enforce a Federal permits program for the State of Vermont upon interim approval expiration.

II. Proposed Action and Implications

A. Analysis of State Submission

The analysis contained in this document focuses on specific elements of Vermont's title V operating permits program that must be corrected to meet the minimum requirements of 40 CFR part 70. The full program submittal, technical support document (TSD), dated April 19, 1996 entitled ''Technical Support Document—Vermont Operating Permits Program'', which contains a detailed analysis of the submittal, and other relevant materials are available for inspection as part of the public docket. The docket may be viewed during regular business hours at the address listed above.

1. Title V Program Support Materials

Vermont's title V program was submitted by the State on April 28, 1995 (PROGRAM). The submittal was found to be administratively complete on June 12, 1995. The PROGRAM consisted of a Governor's letter, program description, Attorney General's legal opinion, permitting regulations and enabling legislation, and permitting program documentation. Included with the PROGRAM submittal was a draft implementation agreement which will be finalized by EPA and Vermont. The

[1] Note that states may require applications to be submitted earlier than required under section 503(c). See Subchapter X, Section 5–1005 of Vermont's rules.