to perform critical functions are not adversely affected when the airplane is exposed to high intensity radiated fields.

For the purpose of this special condition, the following definition applies:

Critical Functions. Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

2. *Engine Torque Loads*. In lieu of compliance with § 25.361(b), compliance with the following must be shown:

(b) For turbine engine installations, the mounts and local supporting structure must be designed to withstand each of the following:

(1) The maximum torque load, considered as limit, imposed by:

(i) sudden deceleration of the engine due to a malfunction that could result in a temporary loss of power or thrust capability, and that could cause a shutdown due to vibrations; and

(ii) the maximum acceleration of the engine.

(2) The maximum torque load, considered as ultimate, imposed by sudden engine stoppage due to a structural failure, including fan blade failure.

(3) The load condition defined in paragraph (b)(2) of this section is also assumed to act on adjacent airframe structure, such as the wing and fuselage. This load condition is multiplied by a factor of 1.25 to obtain ultimate loads when the load is applied to the adjacent wing and fuselage supporting structure.

Issued in Renton, Washington, on September 17, 1997.

Vi L. Lipski,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–25509 Filed 9–25–97; 8:45 am]

BILLING CODE 4910–13–M

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that requires 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 diseases (STD's), including human immunodeficiency virus (HIV). This requirement is established in order to provide consumers with essential information regarding the safe use of these products.

EFFECTIVE DATE: March 25, 1998.

FOR FURTHER INFORMATION CONTACT: Donald E. Marlowe, Center for Devices and Radiological Health (HFZ–100), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–2444.

SUPPLEMENTARY INFORMATION:

I. Background

It is estimated that over 1 million persons in the United States are infected with HIV (Ref. 1). Although nonsexual transmission can occur, HIV is transmitted primarily through sexual contact. With the prevalence of HIV infection and the risk of transmission of other STD's, the importance of the quality of an effective barrier to the transmission of infection is crucial. Because latex membranes, such as condoms and medical gloves, are effective barriers against the spread of various diseases, including hepatitis, HIV, and other STD's (Refs. 2, 4, and 5), the Centers for Disease Control and Prevention and the Surgeon General of the Public Health Service have recommended that latex condoms be used according to instructions with every act of intercourse for maximum protection against STD's (Ref. 3).

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 conditions. Exposure to these environmental conditions degrade the film progressively over time and may result in bursts, rips, tears, or seepages that allow the transmission of disease.

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 of 1989 (Ref. 6). At the laboratories of the FDA/Washington study, packaged and unpackaged latex condoms were exposed to 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.

Based upon these findings, using standards established by the American Society for Testing and Materials (ASTM), and following meetings with condom manufacturers, the agency published in the **Federal Register** of May 24, 1996 (61 FR 26140), a proposed rule that would require latex condoms to be labeled with an expiration date. Specifically, FDA proposed that, to ensure visibility of the expiration date by customers, an expiration date must 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 establish the expiration date, FDA proposed 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.

If the latex barrier properties are adequate (i.e., pass the manufacturer's physical and mechanical integrity tests) after undergoing the 70 °C/7-day and 40 to 50 °C/90-day tests, the proposal provided for that product to 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.

This final rule incorporates the principles described in the proposed rule and requires latex condoms to bear expiration dates after being subjected to appropriate testing. When a labeling change is made to comply with this rule, products currently cleared for marketing would not be required to submit a new 510(k). FDA will modify agency guidance to reflect this policy. Of course, latex condom products that have not been cleared for marketing are still required to submit to FDA a 510(k) premarket notification.

II. Summary of Comments

The agency received only three comments on the proposed rule, two of which addressed the economic impact of the rule, but not its content. The remaining comment, submitted by a trade association, was generally supportive of the proposed rule but raised several issues warranting further consideration.

A. General

1. The comment stated that the proposed rule did not distinguish between the testing requirements applicable to new products as opposed to currently marketed products. The comment suggests that some currently marketed products may already be labeled with an expiration date that has been cleared by the agency. To require these products to undergo testing following accelerated and intermediate aging would be unnecessarily redundant if the existing cleared expiration date has been established by real time testing.

The agency agrees that, where a product bears an expiration date based on appropriate integrity tests following storage in real time, accelerated aging and testing are redundant and should not be required. This position is reflected in the final rule that has been modified accordingly in new § 801.435(f).

The agency stresses that testing data supporting an expiration date must be available for inspection by the agency, regardless of whether the agency previously cleared product labeling which bears an expiration date. If such data is not available for inspection, the manufacturer must generate shelf life data with accelerated and real time storage and testing.

2. The comment suggested that the introductory paragraph of proposed § 801.435(d) be modified to read,

> ''The expiration date must be supported by the data from reasonable quality control tests demonstrating the physical and mechanical integrity of the product after three discrete and typical lots of the product have been subjected to each of the following conditions.'' (Emphasis added.)

The language in the proposed rule stated, ''* * * after three discrete and random lots of the same product have been subjected to each of the following conditions.'' (Emphasis added.)

The agency recognizes that manufacturers of new products, or new formulations, may not have produced a sufficient number of lots to allow a truly random selection for testing. The purpose of selecting random lots is to ensure that the tests are conducted on products that are representative of the products being produced. The word ''representative'' is more commonly used in the context of sampling analyses than its synonym, ''typical.'' The agency believes the comment that suggested substituting the word ''typical'' for ''random'' is appropriately addressed by substituting the word ''representative'' for the word ''random.'' The final regulation has been modified accordingly.

The agency also recognizes that the proposed requirement to conduct testing on lots of the same product needs further clarification in light of the agency's October 1989 ''General Guidance for Modifying Condom Labeling to Include Shelf Life,'' that states that shelf life data may not be needed for each variation from a ''standard'' condom. The agency continues to consider its October 1989 guidance to be an accurate statement of agency policy. FDA recognizes that a manufacturer may produce several variations of a tested condom, including variations of packaging, design (e.g., texture, thickness, etc.), latex formulation (including color additives), dusting powders, spermicides, desensitizers, and lubricants. As stated in the agency guidance, ''FDA recognizes that some variations may not warrant separate shelf life testing.'' Certain variations, however, may affect condom strength, integrity, and even response to environmental factors in a variety of ways. Therefore, the regulation has been revised to state in § 801.435(g) that, if a manufacturer applies shelf life data to a variation of the tested condom, the manufacturer must document and provide upon request appropriate justification.

3. The comment stated that the requirement that the condoms to be tested be stored unpackaged for the maximum amount of time the manufacturer allows the product to remain unpackaged, before packaging, storage, and testing, is unnecessary and overly burdensome. The comment states that this provision would require manufacturers to develop new data for holding periods with respect to products that are currently labeled with approved expiration dating.

The agency disagrees that this provision is unnecessary and overly burdensome. Degradation of latex films is cumulative. Shelf life data derived from a lot of condoms that were packaged the day following production may not necessarily be applicable to the same product that is left unpackaged for 180 days. In requiring a manufacturer to conduct tests on products that have been stored unpackaged for the maximum time the manufacturer allows the product to remain unpackaged, the agency is ensuring that the integrity of the tested products would be representative of the products receiving the greatest exposure to environmental conditions. Thus, shelf life data generated by testing these products could be applied with the greatest confidence.

As discussed in comment 1 in section II.A of this document, the agency believes that currently cleared expiration dates that have been determined by real time testing of the product may continue to be applied. In the event this real time testing did not account for time periods products remain unpackaged, however, manufacturers would be required to perform confirmation testing to account for maximum holding periods for their products that are already labeled with an expiration date. This testing will be initiated by the effective date of the

regulation. Until the confirmation tests are completed, the previously cleared products may remain on the market labeled with the expiration date based on previous real time testing. The regulation has been modified in § 801.435(f) to clarify this issue.

4. The comment objected to the requirement that new premarket notification submissions, required under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)), for latex condoms should include data to establish labeled expiration dates, especially in light of the agency's allowance that such data need only be held as part of the manufacturing records for currently marketed products. This comment suggested that new 510(k) submissions only be required to state the claimed expiration dating period, and identify whether it has been tentatively established through accelerated aging or established under real time conditions consistent with the requirements of § 801.435.

The agency agrees with this comment. The agency believes that a 510(k) submission that includes statements that appropriate tests were performed and that the condoms passed appropriate mechanical and physical integrity tests should not generally have to include underlying test data. FDA intends to revise its existing guidance on 510(k) submissions for latex condoms to reflect its position that underlying data for expiration dating should not be submitted. All shelf life data generated under the requirements of this final rule shall be retained in each company's files, as required by § 820.180 (21 CFR 820.180), and shall be made available upon request for inspection by FDA.

5. The comment requests that the agency draw a clear distinction in the regulation between closed-ended latex condoms, that are used for prevention of STD transmission and pregnancy, and open-ended condom catheters that are used for continence and chronic care.

The agency confirms that the rule does not apply to open-ended condom catheters. The agency, however, does not believe that the regulation requires any modification to clarify this issue. As proposed and finalized, the regulation states that ''this section applies to the subset of condoms as identified in § 884.5300, and condoms with spermicidal lubricant as identified in § 884.5310 of this chapter, which products are formed from latex films.'' Sections 884.5300 and 884.5310 (21 CFR 884.5300 and 884.5310) specifically describe the intended uses of closed ended condoms. The regulation, therefore, clearly establishes that open-ended condom catheters are not subject to this rule.

Moreover, in order to avoid future confusion, the agency is taking this opportunity to clarify the fact that this rule does not apply to female condoms. Female condoms are distinguished from the products identified in the scope of this rule in two significant details: (1) Sections 884.5300 and 884.5310 do not describe female condoms, and (2) female condoms are formed from polyurethane, not latex.

6. The agency is also taking this opportunity to clarify its position regarding latex condoms that are sold with spermicidal lubricants. Such products are currently cleared for marketing provided they bear labeling that reflects expiration dates and statements relating to the spermicidal agents. On August 9, 1982, in response to a petition by Schmidt Laboratories, Inc., FDA issued an order reclassifying a condom with a spermicidal lubricant (nonoxyl-9) from class III to class II. In the preamble to the final rule published in the **Federal Register** of October 29, 1982 (47 FR 49021), which reclassified generic condoms with spermicidal lubricants into class II, FDA advised that the generic device was reclassified into class II only insofar as its labeling bore an expiration date for the spermicidal agent and the following statement ''The expiration date on this product applies only to the spermicidal agent in it.''

Because the effectiveness of condoms with spermicidal lubricants depends on both the integrity of the latex and the stability of the spermicide, the expiration date should warn against use of the product after a date that either the spermicide or the latex could be ineffective. FDA is advising that it would consider a condom with spermicidal lubricant that bears the earlier expiration date that is related to the condom's latex or spermicidal properties, substantially equivalent to a class II condom with spermicidal lubricant under § 884.5310.

FDA has added § 801.435(h) to the final rule to state that if a latex condom contains spermicide, and the expiration date based upon spermicidal stability testing is different from the expiration date based on latex integrity testing, the product shall bear only the earlier expiration date. Accordingly, the statement required by the August 9, 1982, Reclassification Order that ''The expiration date on this product applies only to the spermicidal agent in it'' would be incorrect and shall not appear on the labeling of latex condoms with spermicidal lubricants following the effective date of this regulation. Any labeling changes to comply with § 801.435(h) will not require the filing of a new 510(k).

This regulation does not impose new testing requirements to determine expiration dates based upon spermicide stability. Manufacturers should continue to perform the appropriate tests to determine spermicide amount and biological activity that have supported the expiration dating for the spermicide in the past.

B. Comments on the Economic Impact

7. The agency received two comments addressing the economic impact of the proposed rule. One comment stated that the agency significantly underestimated the cost burden of establishing an expiration date for latex condoms because, in order to accurately establish shelf life data, a manufacturer would need to test packaging integrity, packaging material, and lubricants used, as well as latex compound integrity.

The agency disagrees. The testing requirements in the proposed and final rules would provide shelf life data based upon the aggregate effect of the factors identified by the comment. The agency believes that no real purpose would be served by additionally requiring the suggested tests.

8. One comment suggested that requiring manufacturers of new products to submit shelf life data with their 510(k) submissions subjects manufacturers of those products to an additional administrative burden that is unnecessarily restrictive and may delay the public access to new and improved products.

As discussed in comment 4 in section II.A of this document, the agency has revised its position and is not requiring that manufacturers submit shelf life data with their 510(k) submissions. Instead, shelf life data shall be retained in each company's files, as required by § 820.180, and shall be made available upon request for inspection by FDA.

C. Comments on the Estimated Recordkeeping Burden

9. One comment stated that the agency significantly underestimated the recordkeeping burden that would be created by shelf life testing. The comment stated that the number of condom variations that would require testing is much higher than estimated, however, no guidance was given for estimating the number more accurately. The comment also stated that the industry practice in gathering real time testing data is to test the product each year. That is, instead of testing the product at 0 days, 7 days (accelerated

aging), 90 days (intermediate aging), and 5 years (real time) as discussed in the paperwork burden section of the proposed rule (61 FR 26140 at 26143), manufacturers would actually be testing at 0 days, 7 days, 90 days, 1 year, 2 years, 3 years, 4 years, and 5 years. This would represent a doubling of the testing burden for each product over the course of 5 years.

The agency agrees that the testing of products in intermediate years 1, 2, 3, and 4 is an appropriate and customary method of gathering real time shelf life data. This would be reflected in the burden chart as a doubling of the estimated burden. However, in response to other comments, the agency has required manufacturers of latex condoms that already have expiration dating data, based on real time testing, to do only a confirmation test, as appropriate. These products would be required to be tested only once in 5 years. The Paperwork Reduction Act analysis is modified to address these changes in testing frequency.

Moreover, the agency has adjusted the Paperwork Reduction statement to address the comment stating that manufacturers would be required to collect expiration dating data for more than one variation of a standard condom. The agency has attributed an average of two variations that would require testing for each standard condom considered in its original estimate. Furthermore, the agency has provided that manufacturers may apply expiration dating data collected on a standard to a variation of the standard, provided the manufacturer documents its justification. The burden estimates have been modified to reflect the cost of such documentation.

The Paperwork Reduction Act analysis is further modified to annualize the cost of shelf life testing over 5 years. Whereas the proposed Paperwork Reduction Act analysis reflected an annual burden of testing products at 0 days, 7 days, 90 days, and 5 years, the agency has determined that it would be more appropriate to consider the testing of products at 0 days, 7 days, 90 days, 1 year, 2 years, 3 years, 4 years, and 5 years, as a burden spread out over the 5 years it would take to complete the tests.

III. 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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by Subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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 regulation requires physical and mechanical integrity tests. Because condom manufacturers routinely conduct such tests on their products as part of their quality control practices, the required testing would affect manufacturers primarily by establishing storage conditions prior to testing such products, and increasing sampling sizes subjected to testing. This rule also requires a labeling change. However, the 180-day time period between the publication date and effective date of this rule will allow most manufacturers to exhaust their existing supply of labels. Accordingly, the agency certifies that the final rule will not have a significant economic impact on small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

V. Paperwork Reduction Act of 1995

This final 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 collections are shown below and an estimate of the annual recordkeeping and periodic 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.

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

Description: These information collection requirements apply to manufacturers of latex condoms. This rule expands the labeling of latex condoms to include an expiration date. The expiration date must be supported by data from quality control tests demonstrating physical and mechanical integrity of three sample lots of the product being tested that were stored under accelerated and real time aging conditions. Quality control testing under accelerated aging conditions must include tests of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by: (1) Storage of the packaged product at 70 °C (plus or minus 2 °C) for 7 days; (2) 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 the packaged product at a monitored or controlled temperature between 15 and 30 °C for the lifetime of the product (up to 5 years). Manufacturers who already have shelf life data based upon real time testing are not required to perform the 7-day and 90-day accelerated aging testing.

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 have degraded. The effectiveness of latex condoms as a barrier 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 the product.

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 the likely effectiveness of the product.

Section 510(h) of the act, 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 per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
801.435(d)	58	1	58	96	5,568	$1,856[1]	$94,655[2]

[1] Capital costs are one time start-up costs and consist of a revision of policies and procedures. These costs have been annualized over a period of 5 years.

[2] The annual burden reported here represents the recordkeeping burden of testing a product of 0 days, 7 days, 90 days, 1 year, 2 years, 3 years, 4 years, and 5 years. The cost of this burden is annualized over the 5-year period required to conduct all the necessary testing.

The agency received one comment on the Paperwork Reduction Act statement of the proposed rule. As discussed in comment 9 in section II.C of this document, the agency has adjusted the estimated burden according to the suggestions made by the comment. The revised estimated burden has been adjusted to include the burden of testing a product at intermediate years during real time aging, and the burden of testing more than one variation on a standard condom. The revised estimated burden reflects a burden annualized over the 5 years required to perform all necessary testing.

Persons are not required to respond to a collection of information unless it displays a currently valid OMB control number. This final rule contains information collection requirements which have been submitted to OMB for approval. FDA will publish a notice in the **Federal Register** prior to the effective date of this final rule of OMB's decision to approve, modify, or disapprove the information collection requirements.

VI. 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 and Prevention, ''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. WS–CO2–1), vol. 1, IXth International Conference on AIDS/IVth 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 Vulcanizates,'' *Journal of Natural Rubber Research*, vol. 2, No. 4, pp. 201–213, 1987.

9. Barker, L. R., ''Accelerated Long-Term Ageing of Natural Rubber Vulcanizates, Part 2: Results From Aging 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,'' FDA Guidance Document.

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, 21 CFR part 801 is amended as follows:

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 of this chapter, which products are formed from latex films.

(b) Data show that the material integrity of latex condoms degrade 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 paragraphs (d) and (h) of this section.

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

(d) Except as provided under paragraph (f) of this section, the expiration date must be supported by data demonstrating physical and mechanical integrity of the product after three discrete and representative lots of the 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 physical and mechanical integrity tests commonly used by industry 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 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 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) Products that already have established shelf life data based upon real time storage and testing and have such storage and testing data available for inspection are not required to confirm such data using accelerated and intermediate aging data described in paragraphs (d)(1) and (d)(2) of this section. If, however, such real time expiration dates were based upon testing of products that were not first left unpackaged for the maximum amount of time as described in paragraph (d)(3) of this section, the real time testing must be confirmed by testing products consistent with the requirements of paragraph (d)(3) of this section. This testing shall be initiated no later than the effective date of this regulation. Until the confirmation testing in accordance with paragraph (d)(3) of this section is completed, the product may remain on the market labeled with the expiration date based upon previous real time testing.

(g) If a manufacturer uses testing data from one product to support expiration dating on any variation of that product, the manufacturer must document and provide, upon request, an appropriate justification for the application of the testing data to the variation of the tested product.

(h) If a latex condom contains a spermicide, and the expiration date based on spermicidal stability testing is different from the expiration date based upon latex integrity testing, the product shall bear only the earlier expiration date.

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

(j) As provided in part 820 of this chapter, all testing data must be retained in each company's files, and shall be made available upon request for inspection by the Food and Drug Administration.

(k) Any latex condom not labeled with an expiration date as required by paragraph (c) of this section, and initially 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n) and 352(a) and (f)).

Dated: August 20, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–25587 Filed 9-25-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8731]

RIN 1545–AU92

Section 42(d)(5) Federal Grants

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final regulations with respect to the low-income housing tax credit relating to the application of section 42(d)(5) to certain rental assistance programs under section 42(g)(2)(B)(i). The regulations clarify that certain types of federal rental assistance payments do not result in a reduction in the eligible basis of a low-income housing building.

DATES: These regulations are effective September 26, 1997.

FOR FURTHER INFORMATION CONTACT: Christopher J. Wilson, (202) 622–3040 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

Temporary regulations (TD 8713) and a notice of proposed rulemaking cross-referencing the temporary regulations were published in the **Federal Register** for January 27, 1997 (62 FR 3792, 3848). Those regulations provide that certain federal rental assistance payments made to the owner of a building on behalf of low-income tenants are not federal grants with respect to a building or its operation that require a reduction in the building's eligible basis under section 42(d)(5) of the Internal Revenue Code (Code). These payments include rental assistance payments made under section 8 of the United States Housing Act of 1937 (Act) (42 U.S.C. 1437f), certain payments made under section 9 of the Act (42 U.S.C. 1437g), and payments made under such other programs or methods of rental assistance as may be designated in the **Federal Register** or the Internal Revenue Bulletin. The notice of proposed rulemaking indicated that comments would be considered on those areas addressed in the temporary regulations. Written comments responding to the notice of proposed rulemaking were received. There was no request for a public hearing, and no public hearing was held. After consideration of all the written comments, the proposed regulations have been adopted, without change, by this Treasury decision.

Summary of Comments

One commenter suggested that the final regulations provide additional guidance for state agencies to use in determining whether similar programs beyond those described in the regulations should be considered grants that cause a reduction in a building's eligible basis under section 42(d)(5) of the Code. The final regulations do not adopt this suggestion. The scope of this regulation is limited to specified rental assistance payments that are not grants requiring a reduction in a building's eligible basis and any additional payments the Secretary may designate in the future.

Another commenter suggested that § 1.42–16(c)(3) should be deleted if it is intended to impose conditions beyond the restrictions under section 9 of the Act, because the Service is improperly infringing upon the Department of Housing and Urban Development's (HUD) authority to provide subsidies under section 9. The final regulations do not adopt this suggestion. Section 1.42–16 does not interpret HUD's authority for paying subsidies under section 9; it describes the extent to which section 9 payments may be made without a reduction in a building's eligible basis under section 42(d)(5) of the Code. The conditions imposed on section 9 payments in § 1.42–16(c)(3) serve to differentiate section 9 assistance for operating expenses that function in a manner similar to rental assistance payments under section 8 of the Act from section 9 assistance that is applied to uses more closely associated with operational expenses requiring a reduction in a building's eligible basis under section 42(d)(5).

This commenter also suggested that if § 1.42–16(c)(3) were to be retained, it should be clarified to provide that actual operating costs be determined by HUD and/or the appropriate public housing agency. The commenter reasons that HUD is already making this determination in the context of deciding the proper amount of assistance to make