

LATEX CONDOMS AND ACCESSORIES

Summary of U. S. Medical Device Requirements

Operation	Register	List	510(k)	PMA	GMP	Color Additive Petition
Repacker (unrolled or from bulk) or relabeler. Distributes under own name	Yes: 807.20(a)(3)	Yes: 807.20(a)(3) Preamble No.7, FR 8/25/78	No: 807.85(b) Unless repacking affects the condom or alters substantive labeling.	No	Yes: 820 Due to the nature of condoms, the packaging operation is a significant step and should be carefully monitored	No
Boxes previously tested/wrapped condoms for distribution under own name. No change in existing wrapper labeling, but box labeled by distributor.	Yes: 807.20(a)(3)	Yes: 807.20(a)(3) Preamble No.7 FR 8/25/78	No: 807.85(b)	No	Yes: 820 Assure packaging has no deleterious effect on the condom and box labeling is accurate	No
Contract packager or labeler.	No	No	No	No	Primary manufacturer must assure that GMP is met, Preamble No. 33, FR 7/21/78.	No
Condom being clinically investigated under IDE.	No: Exempt under 812.1(a)	No: Exempt under 812.1(a)	No: Exempt under 812.1(a)	No: Exempt under 812.1(a)	No: But must have a QA system, 812.5, 812.20(b) 812.27, 812.140(p), see 501(c)	No: Exempt under 812.1(a)
Manufactures/distributes to retail level an accessory (e.g., lubricant, storage case for unwrapped condom) specifically labeled for use with a condom or other medical application.	Yes	Yes	Yes	No: Unless found not equivalent under 510(k)	Yes: 820	No: Unless color is not FD&C approved.

TAB-7

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 29850

October 16 1989

To: All U.S. Condom Manufacturers, Importers and Repackagers

Re: Expiration Date of Condoms

The Food and Drug Administration (FDA) received requests from the Health Industries Manufacturers Association (HIMA) and several manufacturers for guidance on the regulatory requirements for adding shelf life dating on latex condoms. In response to these requests, FDA developed the attached guidance document. If you intend to modify your condom labeling to include an expiration date, you must submit a premarket notification [510(k)] to the FDA per the guidance document.

Expiration dating for the drug component of the condom with spermicidal lubricant is currently required in accordance with 21 CFR 211.137. Data supporting the expiration date of the drug component is not sufficient to support a shelf life claim for the combined product. Therefore, manufacturers of this type of product must submit data, per the guidance document, to support the expiration date of the spermicide/lubricant/condom combination.

FDA has prepared this suggested format as a guidance for use in submitting the required information. All 510(k)'s must be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

The information requirements above also apply to any new condom being introduced to the market if the labeling contains an expiration date. This requirement is in addition to the information generally provided for any premarket notification [510(k)] in accordance with 21 CFR 807.87.

If you have any questions, please contact Raju G. Kammula, D.V.M., Ph.D. at (301) 427-1180.

Sincerely yours,

Robert L. Sheridan
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Attachment

**GENERAL GUIDANCE for MODIFYING
CONDOM LABELING to INCLUDE SHELF LIFE**

October 1989

**Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
1390 Piccard Drive
Rockville, Maryland 20850**

INFORMATION ON SUBMITTING A PREMARKET NOTIFICATION (510K) FOR CONDOM LABELING MODIFICATION TO INCLUDE SHELF LIFE

If a manufacturer, repackager or importer of condoms intends to modify the product labeling to include a shelf life or expiration date, a premarket notification (510(k)) must be submitted to the Food and Drug Administration (FDA). FDA requires data from real time aging of condoms to support the labeling modification. FDA, in the absence of real time aging data, will allow a tentative expiration date based on accelerated aging data, provided the manufacturer also initiates studies to determine the real time shelf life. Appropriate records are to be maintained for FDA inspection and also, when real time self life is confirmed, the manufacturer should notify FDA in a supplement to the 510(k). In the event that the real time aging data does not support the tentative expiration date, the manufacturer should immediately inform FDA and take all necessary steps to correct the labeling. In addition, a supplement to the 510(k) must be submitted amending the expiration date. FDA will accept test methods specified in American Society for Testing and Materials (ASTM) Standard Specifications for RUBBER CONTRACEPTIVES (CONDOMS), D 3492, or any other demonstrably valid method for accelerated testing. For non-latex condoms, and for condoms that contain a spermicidal lubricant, details of the shelf life test methodology need to be provided.

Manufacturers must provide separate shelf life data or an appropriate justification in lieu of data, for why such data are not required for each variation from a "standard" condom. For example, if an unlubricated condom in a foil pack is considered a "standard" condom, then manufacturers must evaluate each variation of packaging; design (texture, thickness, etc.); latex formulation (including color additives); dusting powders; spermicides; desensitizers and lubricants.

FDA recognizes that some variations may not warrant separate shelf life testing and the manufacturer, repackager, or importer may provide appropriate justification in lieu of data.

To expedite the review process, FDA has prepared this suggested format as a guidance for use in submitting the required information. All 510(k)'s must be submitted in duplicate, to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

If you have any questions, please contact Raju G. Kammula, D.V.M., Ph.D. at 301- 427-1180.

**SUGGESTED FORMAT FOR A PREMARKET NOTIFICATION (510(K))
FOR LABELING MODIFICATIONS TO IDENTIFY
SHELF LIFE (END USE LIFE) FOR CONDOMS**

1. Applicant: _____
Name and Address:

2. Contact Person: _____
Name

Title

Phone number

3. Manufacturer: _____
Name and Address:

4. Product Identification:

a. Trade Name: _____

b. 510(k) Number, if applicable: _____ or

c. Pre-amendment Device-Year Introduced: _____

5. Packaging System: _____
Provide a complete description of the products primary package.

6. Accelerated Aging Test Method:

a. ASTM Method: _____

b. Other: If testing method differs from the ASTM method, a detailed description must be provided as an attachment.

LATEX CONDOMS AND ACCESSORIES

Summary of U. S. Medical Device Requirements

Operation	Register	List	510(k)	PMA	GMP	Color Additive Petition
U.S. Manufacturer/distributor of condoms that meet established standard (ASTM, ISO, British, etc.)	Yes: 807.20	Yes: 807.20(a)	Yes: 807.81(a)	No	Yes: 820	No: Unless color is not FD&C Approved
U.S. Manufacturer/distributor of condoms that significantly deviate from established standard.	Yes: 807.20	Yes: 807.20(a)	Yes: 807.81(a) Draw equivalency to a condom on the U.S. market before 5/28/78	No: Unless found not equivalent under 510(k)	Yes: 820	No: Unless color is not FD&C approved
Manufactures and distributes condom with viricidal claims	Yes: 807.20	Yes: 807.20(a)	No	Yes	Yes: 820	No: Unless color is not FD&C approved
Manufactures/distributes condom composed of new/unique material	Yes: 807.20	Yes: 807.20(a)	Yes: 807.81(a) (2) (f)	No: Unless found not equivalent under 510(k)	Yes: 820	No: Unless color is not FD&C approved
Specification developer and distributor	Yes: 807.20(a) (1) Preamble No.5 FR 8/23/77	Yes: 807.20(a) (1)	Yes: 807.81(a)	No: Unless found not equivalent under 510(k) or has viricidal claims.	Yes: 820, 824 Must assure that specifications are met	No: Unless color is not FD&C approved
Specification consultant; no distribution	No: Preamble No. 5, FR 8/23/77	No	No	No	No	No
Contract manufacturer of finished condoms.	Yes: 807.20(a) (2)	No: 807.20(a) (2)	No: 807.81(a)	No	Yes: 820	No
Distributes U.S.-made condom. No specification development or repackaging/relabeling.	No: 807.65(g)	No	No: 807.85(b)	No	No	No
Initial distributor (importer) of foreign-manufactured condom. No specification development or repackaging / relabeling	Yes: 807.20(a) (4)	No: However, must provide name and address of foreign manufacturers 807.22(c) (3) or may list if authorized and sole distributor 807.40(b).	Yes: 807.81(a) or 807.82(a), unless foreign manufacturer or another Initial distributor has filed on the same product	No: Unless found not equivalent under 510(k)	Yes: 807.3(d), 820.108, 820.20(a) (3)	No: Unless color is not FD&C Approved
Foreign manufacturer selling to U.S. Initial distributor (importer)	No: Encouraged to (807.40(a))	Yes: Unless sole initial distributor is authorized to list for foreign manufacturer 807.40(b)	Either foreign manufacturer or initial distributor may submit	No: Unless found not equivalent under 510(k) or has viricidal claims	Yes: 820	No: Unless color is not FD&C Approved
Foreign manufacturer selling direct to U.S. retail store or end-user.	No: Encouraged to (807.40(a)) Note each initial retail store or end-user is considered an importer (initial distributor) subject to registration	Yes: 807.40(b)	Either Foreign manufacturer or initial distributor may submit	No: Unless found not equivalent under 510(k) or has viricidal claims	Yes: 820	No: Unless color is not FD&C Approved
Repacker (unrolled or from bulk) or relabeler. Distributes under own label. Adds lubricant, spermicide, color, etc.	Yes: 807.20(a) (3)	Yes: 807.20(a) Preamble No.7 FR 8/25/78	Yes: 807.81(a) (3) (f)	No: Unless found not equivalent under 510(k)	Yes: 820	No: Unless color is not FD&C Approved

If such components are not available, then all constituents in the components or in compounding materials which could present a hazard to health must be removed from the devices or limited to an amount that will not present such a hazard.

The content of water soluble proteins in raw latex can be reduced by centrifugation and other techniques. Thus, a finished latex device manufacturer may deem it appropriate to specify the water soluble protein content of the raw latex to be purchased. Then, there should be adequate assurance that each lot of latex received meets the protein content specification.

However, unless the raw latex is completely deproteinized, further processing of the resulting devices may be needed to remove or reduce the residual water soluble proteins.

4. MANUFACTURING AND QA PROCESS VALIDATION

To meet good manufacturing practices requirements, the processes used to control water soluble proteins must be developed, evaluated (validated), documented and, thereafter, controlled. Likewise, the process for measuring proteins must be validated and documented. Data from validation of the testing method for proteins must assure that the leaching, cleaning or treating processes being used adequately reduce water soluble proteins to or below the level in the company's specification.

If you have any questions about these procedures, please contact:

Andrew Lowery, Chief, Technical Assistance Branch, at 800-638-2041 or, if you are located in Maryland, at 301-443-6597. Our FAX is 301-443-8818.

Sincerely yours,

John Stigi
Director
Division of Small Manufacturers
Assistance, HFZ-220
Office of Training and Assistance
Center for Devices and
Radiological Health



May 1, 1991

• TO ALL MANUFACTURERS OF LATEX DEVICES:

The Food and Drug Administration (FDA) has become aware of an increase in the number of reported adverse reactions and deaths associated with the use of one brand of enema devices with cuffs made of latex. During its investigation of enema devices, the FDA also reviewed the medical literature, data in FDA files, and other sources. Information about reactions to latex devices were found in these various sources. As a result of this review, the FDA is concerned that deficiencies in the manufacturing process for latex devices could be a contributing factor for some of these adverse events. That is, insufficient leaching or insufficient surface treatment by some manufacturers will not remove leachable proteins that are associated with these reactions.

The concern by the FDA is not meant to be an implication of the latex device industry. The FDA is, however, aware that the latex industry is always interested in meeting emerging health care needs. Consequently, the following advice has been developed by FDA in an effort to minimize the possibility that latex contaminants are either a source or a contributing factor in the adverse reactions attributed to various types of latex devices.

FDA's advice is as follows:

1. LEACHING

Current investigations and conventional manufacturing techniques indicate that one way of minimizing reactions is to remove as much of the water soluble proteins as possible from the latex devices. This removal is primarily done by: controlling the leaching process; assuring that the leach tanks contain hot water that is continually refreshed; and, immersing the devices in the leaching tanks for an appropriate time.

2. POST CURE PROCESSING

Depending on the nature of the latex device, manufacturing process and intended use, some latex devices may also need off-line washing with hot water after completion of the curing process. Also, surface treatment of the cured latex device with chlorine or other agents may denature surface constituents, such as water soluble proteins.

3. LATEX SPECIFICATIONS

When establishing the design requirements for any device, the components used must be evaluated to assure that they are safe and effective for their intended application. Where feasible, manufacturers should specify components that do not contain ingredients which are known to present a hazard to health.

c. Shelf Life: _____

7. Real Time Testing Procedures: The manufacturer should provide a response to 7 (a)-(d) with the original 510(k); however, if a tentative expiration date is requested, the manufacturer should notify FDA, in a supplement to the 510(k), confirming the real time shelf life (7 (d)).

a. Storage conditions: _____

b. Sample size* and test interval: _____
* statistically valid sample

c. Specific testing methods: _____
Identify standard method or in-house testing procedure.

d. Real Time Shelf Life: _____

