



Medical Alert

March 29, 1991
MDA91-1

Lenore Gelb
(301) 443-3220

*Allergic Reactions to
Latex-Containing Medical Devices*

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), FDA is advising health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly. Patient reactions to latex have ranged from contact urticaria to systemic anaphylaxis. Latex is a component of many medical devices, including surgical and examination gloves, catheters, intubation tubes, anesthesia masks, and dental dams.

Reports to FDA of allergic reactions to latex-containing medical devices have increased lately. One brand of latex-cuffed enema tips was recently recalled after several patients died as a result of anaphylactoid reactions during barium enema procedures. More reports of latex sensitivity have also been found in the medical literature. Repeated exposure to latex both in medical devices and in other consumer products may be part of the reason that the prevalence of latex sensitivity appears to be increasing. For example, it has been reported that 6% to 7% of surgical personnel and 18% to 40% of spina bifida patients are latex-sensitive.

Proteins in the latex itself appear to be the primary source of the allergic reactions. Although it is not now known how much protein is likely to cause severe reactions, FDA is working with manufacturers of latex-containing medical devices to make protein levels in their products as low as possible.



FDA's recommendations to health professionals in regard to this problem are:

- When taking general histories of all patients, include questions about latex sensitivity. For surgical and radiology patients, spina bifida patients, and health-care workers, this recommendation is especially important. Questions about itching, rash or wheezing after wearing latex gloves or inflating a toy balloon may be useful. Patients with positive histories should have their charts flagged.
- If latex sensitivity is suspected, consider using devices made with alternative materials, such as plastic. For example, a health professional could wear a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and patient are sensitive, a latex middle glove could be used. (Latex gloves labeled "hypoallergenic" may not always prevent adverse reactions.)
- Whenever latex-containing medical devices are used, especially when the latex comes in contact with mucous membranes, be alert to the possibility of an allergic reaction.
- If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity and consider an immunologic evaluation.
- Advise patients to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures. Consider advising patients with severe latex sensitivity to wear a medical identification bracelet.

FDA is asking health professionals to report incidents of adverse reactions to latex and other materials used in medical devices. (See the October 1990 *FDA Drug Bulletin*.) To report an incident, call the FDA Problem Reporting Program, operated through the U.S. Pharmacopeia toll-free number: 800-638-6725. (In Maryland, call collect 301-881-0256.) For further information on the clinical aspects of latex sensitivity, call Claudia Gaffey, M.D., Office of Health Affairs, Center for Devices and Radiological Health, at (301) 427-1060.

For a single copy of a reference list on latex sensitivity, write to: LATEX, FDA, HFZ-220, Rockville, MD 20857.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
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TO: Manufacturers, Distributors and Importers of Condom Products

On February 13, 1989, the Food and Drug Administration (FDA) issued a statement of policy regarding the marketing of condom-like products (a.k.a. "Novelty Condoms"). This letter revises and supersedes that policy.

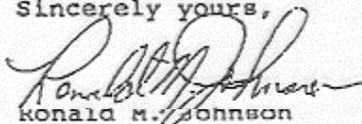
Condoms are medical devices which many consumers rely upon for contraception and prevention of sexually transmitted diseases (STD's), especially AIDS. Therefore, condoms or products that can be used as condoms, must comply with specific condom leak testing requirements as well as other regulatory requirements for medical devices. Some marketers have misinterpreted the 1989 policy and believe it permits the marketing of condoms as novelty items even though they do not comply with these requirements. These novelty products frequently consist of a condom packaged or labeled for adult humor. They are traditionally sold in adult entertainment shops. This situation has caused confusion and may result in the use of these noncompliant products by consumers with the expectation that they are effective in preventing pregnancy and STDs.

Products that can cover the penis with a closely fitting membrane and otherwise have the appearance of a condom are regarded as condoms regardless of packaging or labeling. These products, by form and function, meet the definition of a condom as defined in 21 CFR 884.5300 and must therefore comply with all requirements for condoms including leak testing, compliance with Good Manufacturing Practices regulations, manufacturer registration, product listing, and pre-market notification and clearance.

In order to market a condom-like product which is not subject to the above requirements, the product cannot be usable as a condom in any way. For example, a condom could be rendered unusable by removing the closed end; shredding the sides; sealing the roll in such a way that it cannot be unrolled, or by some other method rendering it equally unusable. Labeling a functional condom as a novelty is not sufficient.

Questions concerning this policy can be directed to Mr. Byron L. Tart by writing to the letterhead address or phoning (301) 594-4639.

Sincerely yours,



Ronald M. Johnson

Director
Office of Compliance
Center for Devices and
Radiological Health

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INFORMATION FOR A LATEX CONDOM 510(k) SUBMISSION
FOR OBSTETRICS-GYNECOLOGY DEVICES BRANCH
DRAFT

The following information should be included for a premarket notification (510(k)) submission for a natural latex rubber condom:

I. Device Description and Material Safety

- A. Identify a legally marketed device, and compare your device to the legally marketed device in terms of intended use, design, materials, specifications and performance. Where applicable, photographs or engineering drawings should be supplied.
- B. Provide the chemical composition of your condom latex formulation, including any additives, e.g., antioxidants, accelerators, etc.
- C. Provide the chemical composition of the dusting agent and the lubricant to be applied.
- D. Provide the chemical composition of the color additive(s) that is used with the condom(s), if applicable. Also, identify the color index number and a reference to the specific color additive listing (21 CFR reference).
- E. Provide biocompatibility data, including mucosal irritation, sensitization, and acute systemic toxicity, on the final product to support its safe use. Protocols, as well as test data and conclusions, from the toxicological testing of the finished condom must be provided. (Please refer to FDA's Tripartite Biocompatibility for Medical Devices Guidance for selecting the appropriate types of tests; TAB 1))
- F. Provide a description of the manufacturing processes instituted to minimize any potential adverse effects of latex hypersensitivity (Please refer to FDA's Safety Alert; TAB 2)

II. Quality Assurance

- A. Provide a detailed description of the air burst test procedure and identify the acceptable quality level (AQL) used by the manufacturer to establish the quality of each condom lot or batch. FDA requires that final product release testing include the International Organization for Standardization (ISO 4074-1:1990(E)) Rubber Condoms - Part 6: Determination of Bursting Volume and Pressure (ISO 4074-6:1984). (Please refer to TAB 3)
- B. Provide a detailed description of the water leakage test procedure and its acceptable quality level (AQL) used by the manufacturer to establish the quality of each condom lot or batch. FDA requires that final product release testing includes water leakage testing per American Society for Testing and Materials, Standard Specification for Rubber Contraceptives (Condoms) (ASTM D 3492-89). (Please refer to TAB 3)
- C. Provide a detailed description of all other in-process and final release test procedures, e.g., tensile strength, elongation, color fastness, packaging integrity, etc., and identify their acceptable quality level (AQL). Also, identify when quality control tests are conducted during the manufacturing process.

- D. Provide a detailed description of the electronic testing procedures, including a description of the electronic testing machine, the machine's specifications, operators manual, and a description of the electronic testing machines' calibration procedures. Also, describe any relationship between the electronic testing machines' calibration procedures and results of physical testing procedures used for product release.

III. Labeling

Provide copies of labels, labeling and advertisements sufficient to describe the device:

- A. the intended use and directions for use (Please refer to FDA's April 7 and July 31, 1987 and February 13, 1989 letters - TAB 4);
- B. a statement that only water based lubricants be used with latex condoms;
- C. the statement, "If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases." This statement should be located on both sides of each individual condom package, on the principal display panel of the outer box and also be included on any package insert. (Please refer to April 8, 1993, letter to condom manufacturers - TAB 5);
- D. the nominal width;
- E. the date of manufacture or an acceptable expiration date; and
- F. a statement of specific contraceptive effectiveness cautionary provision for condoms with spermicidal lubricant. (Please refer to TAB 6)

IV. Shelf Life

Identify if your device labeling includes a proposed shelf life. If applicable specify the proposed shelf life and provide data to support the proposed shelf life. (Please refer to TAB 7.)

V. Safe Medical Device Act (SMDA) Requirement

The Safe Medical Device Act (SMDA) requires all persons submitting a premarket notification submission to include either (1) a statement that you will make available to interested persons upon request, the safety and effectiveness information in this premarket notification that is relevant to an assessment of substantial equivalence or (2) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination is based. Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information that supports a finding of substantial equivalence. The information could be descriptive information about the new and predicate device, or performance or clinical testing information.