This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
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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
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