Attachment B

The following constitute an acceptable set of instructions if protection against sexually transmitted diseases is claimed. You may wish to add additional instructions appropriate for your specific product.

"* Use a new condom every time you have sexual intercourse or other acts between partners which involve contact with the penis.

* Put the condom on after the penis is erect and prior to intimate contact, because lesions, pre-ejaculate secretions, semen, vaginal secretions, saliva, urine, and feces can contain STD organisms.

* Place the condom on the head of the penis and unroll or pull it all the way to the base.

* Leave an empty space at the end of the condom to collect semen. Remove any air remaining in the tip of the condom by gently pressing the air out towards the base of the penis.

* If a lubricant is desired, use water-based lubricants such as _____. Do not use oil-based lubricants, such as those made with petroleum jelly, mineral oil, vegetable oil, or cold cream, as these may damage the condom.

* If the condom breaks or semen spills or leaks out during use, partners should douche or cleanse themselves wherever contact may have occurred, as soon as possible.

* After ejaculation, carefully withdraw the penis while it is still erect. Hold onto the rim of the condom as you withdraw so that the condom does not slip off.

* Store condoms in a cool, dry place.

* If the rubber material is sticky or brittle or obviously damaged do not use it.

* Do not reuse condoms."

An acceptable set of instructions for use for prevention of pregnancy could be similarly constructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 31 1987

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

On April 7, 1987, the Center for Devices and Radiological Health issued a guidance letter to all manufacturers, importers and repackagers of latex condoms. In attachments to the letter, we provided an example of an acceptable general statement of intended use, and acceptable specific instructions to prevent sexually transmitted diseases (STDs), including AIDS.

The example instruction (Attachment B of the April 7 letter) included the following statement on post-coital douching:

> "If the condom breaks or semen spills or leaks out during use, partners should douche or cleanse themselves wherever contact may have occurred, as soon as possible."

In view of the fact that there are currently no well-controlled studies substantiating the effectiveness of douching to prevent STDs in the event of condom breakage or leakage, we do not believe this recommendation is warranted at the present time. Thus current labeling instructions for condoms should not address douching.

Enclosed is the revised Attachment B of the April 7 letter, which reflects this position. Again, it should be emphasized that these are suggested basic instructions for use. We encourage you to write instructions that are specific to your product and in language appropriate for the intended audience.

Sincerely yours,

John C. Villforth
Director
Center for Devices and
Radiological Health

Enclosure

REVISED ATTACHMENT B

The following constitute an acceptable set of instructions if protection against sexually transmitted diseases is claimed. You may wish to add additional instructions appropriate for your specific product.

"* Use a new condom every time you have sexual intercourse or other acts between partners which involve contact with the penis.

* Put the condom on after the penis is erect and prior to intimate contact, because lesions, pre-ejaculate secretions, semen, vaginal secretions, saliva, urine, and feces can contain STD organisms.

* Place the condom on the head of the penis and unroll or pull it all the way to the base.

* Leave an empty space at the end of the condom to collect semen. Remove any air remaining in the tip of the condom by gently pressing the air out towards the base of the penis.

* If a lubricant is desired, use water-based lubricants such as ____. Do not use oil-based lubricants, such as those made with petroleum jelly, mineral oil, vegetable oil, or cold cream, as these may damage the condom.

* After ejaculation, carefully withdraw the penis while it is still erect. Hold onto the rim of the condom as you withdraw so that the condom does not slip off.

* Store condoms in a cool, dry place.

* If the rubber material is sticky or brittle or obviously damaged do not use it.

* Do not reuse condoms."

An acceptable set of instructions for use for prevention of pregnancy could be similarly constructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

FEB 13 1989

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

TO: Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention

This letter is being sent to further explain our policy regarding the labeling of condoms that are intended to prevent pregnancy and/or the transmission of sexually transmitted diseases (STDs).

It is well recognized that condoms are important in reducing the spread of Acquired Immune Deficiency Syndrome (AIDS) and other STDs. Condoms that are intended to prevent pregnancy and/or the transmission of STDs are regulated by the Food and Drug Administration (FDA), and they must meet certain requirements for design, material, manufacturing, and labeling before being marketed.

It has come to our attention that some condoms that are intended to be used to prevent pregnancy or transmission of STDs are not labeled with an explicit intended use: that is, they do not state clearly that they are designed to prevent conception or the transmission of STDs or both. We believe that the labeling must contain a positive statement of the condom's intended use(s). Conversely, if the condom has only one of the two possible intended uses, the labeling must prominently describe which use is excluded. We are asking that you review your product labeling to be sure it conforms to these criteria and that you take action if you are not now meeting these criteria.

If you manufacture, import, or repackage a condom that is intended to prevent conception and/or the transmission of disease and it is not labeled as such, please let us know within 15 days of the receipt of this letter how and when you intend to revise your labeling. This information should be sent to:

Division of Compliance Operations (HFZ-320)
Office of Compliance and Surveillance
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

In the interest of public health, I look forward to receiving your full cooperation. If you have any questions, please telephone Mr. Frank Pipari at (301)427-8040.

Sincerely yours,

Ann B. Holt

Ann B. Holt, DVM
Acting Director
Office of Compliance
and Surveillance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES TAB4 Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 7 1987

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

Because of the heightened interest in reducing the risks of acquiring sexually transmitted diseases (STDs), including Acquired Immune Deficiency Syndrome (AIDS), the Food and Drug Administration (FDA) is providing this guidance to manufacturers, importers and repackagers of condoms.

If designed, manufactured and tested properly, the condom is a barrier that may prevent the transmission of STDs. With the spread of STDs, it has become very important that users be fully aware that latex condoms provide protection, but do not guarantee it, and that protection is lost if condoms are not used properly. Given the urgent public health concerns regarding this issue, FDA urges your cooperation in informing consumers about realistic expectations they should have regarding the protection afforded by condoms, and in educating them about how condoms should be used to maximize protection against STDs.

If you are currently marketing a latex condom and wish to claim that your product provides protection against STDs, you should include appropriate labeling that reflects accurately the realistic expectations a consumer should have about the condom's effectiveness. An example of such labeling appears in Attachment A.

Natural membranes may have a different permeability than latex and may not lend themselves to the same degree of uniformity in manufacture as synthetic materials such as latex. In the interest of prudence, therefore, FDA is requesting that you not label natural membrane condoms for protection against STDs.

FDA is also requesting that all condoms, whether they are labelled for protection against STDs or not, and whether made from latex, natural membrane, or any other material, include adequate instructions for use to maximize the degree of protection they afford. An example of such instructions for use to provide protection against STDs appears in Attachment B.

If you are currently marketing a condom you may change the labeling and instructions for use of your product to implement the guidance provided in this letter without seeking clearance from FDA. However, you must obtain clearance from FDA if you wish to modify significantly your condom's design or manufacturing, or if you wish to use labeling significantly different from that shown in the attachments.

For example, you will need FDA clearance if you wish to make claims that your condom is better than other condoms or that it is specifically designed for AIDS. All new manufacturers of condoms are also required to obtain FDA clearance.

FDA is urging all condom manufacturers to be particularly vigilant in ensuring that their manufacturing and quality control are in keeping with the best available practices. In order to ensure adequate and uniform manufacturing and quality control practices of this industry, FDA intends to strengthen its inspection of domestic and foreign manufacturers for compliance with good manufacturing practices. The Agency will also strengthen its programs for sampling and testing of all marketed condoms, including imported products. By these actions, FDA will help ensure that domestic and imported products meet the same uniform quality. FDA also intends to monitor carefully the labeling, instructions for use, and other information provided to consumers by condom manufacturers to ensure that such information is accurate, balanced, and useful.

In view of the urgency of this matter, I look forward to receiving your full cooperation. If you have any questions, please contact Dr. Lillian Yin on (301) 427-7555.

Sincerely,

John C. Villforth

John C. Villforth
Director
Center for Devices and Radiological Health

Attachments

-- Attachment A

An acceptable statement of intended use for the prevention of transmission of sexually transmitted diseases follows:

> "When used properly, the latex condom may prevent the transmission of many sexually transmitted diseases (STDs) such as syphilis, gonorrhea, chlamydial infections, genital herpes, and AIDS. It cannot eliminate the risk. For maximum protection, it is important to follow the accompanying instructions. Failure to do so may result in loss of protection. During intimate contact, lesions and various body fluids can transmit STDs. Therefore, the condom should be applied before any such contact."

Different wording may be employed, but the wording should convey a balanced description of risks and benefits, and there should be a warning about the loss of protection resulting from improper use.

An acceptable statement of intended use for prevention of pregnancy could be similarly constructed.