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.

2510 X

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.

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.