

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

April 8, 1993

Dear Latex Condom Manufacturer:

The Food and Drug Administration (FDA) is concerned about the lack of clear information in contraceptive labeling with respect to protection from sexually transmitted diseases (STDs), especially the acquired human immunodeficiency syndrome (AIDS). FDA's concern has grown as a result of its interactions with various consumer groups and health professionals. These groups indicate that, in spite of education efforts on both a local and national level, high risk sexual behavior continues and leads to increased incidence of STDs, including human immunodeficiency virus (HIV) infection. FDA believes that clear labeling will help to promote better use of contraceptive products with respect to STD protection.

Thus, FDA believes it is imperative to take additional steps to inform the sexually active population about which contraceptives have the potential to protect against STDs and which do not. This goal of this initiative is to make every consumer of contraceptive products aware of the protection (or lack of protection) offered by each type of contraceptive product against STDs, particularly HIV infection (AIDS).

Based on current information, FDA has determined that the labeling of all latex condoms, including those containing spermicide, should include statements that inform the user about protection against the transmission of STDs.

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", should be placed in a prominent location on both sides of each individual condom wrapper and on the principal display panel of the outer package.

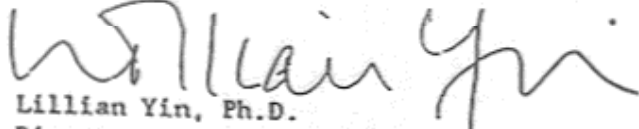
An expanded statement, to be added to the current directions for use, should read, "If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases, including chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis." The labeling statements described above should be prominently displayed in a manner that is clear, likely to be understood by the consumers and not obscured by other information. The labeling changes should be implemented within six months from the date of this letter.

FDA wants to eliminate consumer confusion concerning the effectiveness provided by latex condoms and other contraceptives in protection against the transmission of STDs. We appreciate your prompt attention in helping to educate the public with respect to preventing the spread of HIV infection (AIDS) and other STDs.

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Questions related to labeling should be directed to: Byron Tart, Chief, Device Labeling Compliance Branch, U.S. Food and Drug Administration, HFZ-326, 1390 Piccard Drive, Rockville, Maryland 20850, (301) 427-1342.

Sincerely yours,



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