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
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