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
1390 Piccard Drive
Rockville MD 20850

APR 5 1994

TO: Condom manufacturers and distributors

FROM: Director, Center for Devices and Radiological Health

Because of the increasing reliance on latex condoms as a barrier against HIV and other sexually transmitted diseases, we must continue to take every measure to enhance the quality of these products.

I am therefore requesting that, within 90 days, you add the air-burst test to the finished-product testing of all of your condom products. This test is currently specified in the international ISO standard, and has been proposed as an addition to the American Society for Testing and Materials (ASTM) standard. We are revising our guidance for premarket notification ("510(k)") submissions for latex condoms to reflect this change; you will be receiving copies of our new guidance document as soon as it is ready for distribution. (Recall that our guidance already includes tests for tensile properties and water leakage.)

I realize that many of you are already performing air-burst tests on a routine basis, and that you have been providing the results to us in your 510(k) submissions. The change in our guidance will help ensure that air-burst testing is extended to all of the industry.

Please also note that during inspections of condom manufacturers, we will monitor compliance with air-burst testing of finished products. We are also planning to include the air-burst procedure in our routine testing of condoms on the market. (This program presently includes a water-leakage test more stringent than that specified in the ISO standard.)

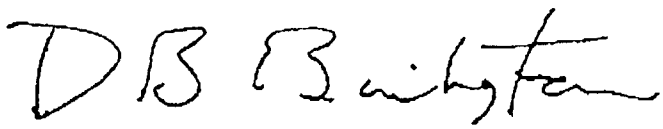
There are several reasons for our increased emphasis on the air-burst test. First, there is increasing evidence that the test may serve as a reliable indicator of a condom's resistance to breakage during use. For example, a 1992 study by Steiner, et al, showed a high degree of correlation between the air-burst test and actual breakage rates in participating couples.(1)

Second, adding air-burst testing to our 510(k) guidance will make it compatible with the anticipated revisions in the condom standard of the American Society for Testing and Materials (ASTM). Although the ASTM standard has not included air-burst tests in the past, we expect that the upcoming version will

specify this type of testing. Thus we expect that condoms fulfilling our new guidance will meet the performance specifications of both the ISO and ASTM standards.

Finally, recent tests conducted at our Winchester Engineering and Analytical Center (WEAC) found that some condom lots did not conform to the existing ISO air-burst test standard. Although all the condom lots examined at WEAC passed the water-leak test, preliminary results showed that six of the 17 lots of newly manufactured condoms in the study failed to conform to the ISO air-burst requirements. Note that an entire lot of condoms is deemed not in conformance with the ISO standard even if only a very small percentage of the condoms in it do not withstand the air-burst test. (In the worst condom lot tested at WEAC, 92 percent of the condoms would have passed the air-burst test.) The WEAC findings demonstrate that there is room for improvement in condom testing, and provide a further basis for our decision to add the air-burst test to our guidances.

I know you share my conviction that condoms should provide as much disease protection as modern production technology will allow, and I am pleased at the level of overall condom quality the industry has been able to achieve thus far. But our criteria cannot remain static. We in the FDA must continue to revise our testing methods as scientific information changes, and the industry should continue to upgrade its quality assurance procedures for these products. I believe that the changes I have described in this letter are important steps in achieving our mutual goal.



D. Bruce Burlington, M.D.

(1) "Study to Determine the Correlation Between Condom Breakage in Human Use and Laboratory Test Results," Contraception, v. 46, pp. 279-88, 1992.