The U.S. Consumer Product Safety Commission is responsible for testing childresistant packages to make sure they protect young children from medicines and dangerous household products. With the help of people like you, manufacturers are able to improve the packages we use, keeping the contents safe from children but easier for the rest of us to open.

Effective child-resistant packages have prevented thousands of poisonings since the Poison Prevention Act was passed in 1970. The use of child-resistant packages on prescription medicines alone may have saved the lives of over 350 children since 1974.

As part of this program, we are testing a child-resistant package to determine if it can be opened and properly closed by an adult who is between 50 and 70 years of age. You may or may not be familiar with the packages we are testing. Take your time, and please do not feel that you are being tested—we are testing the package, not you.

Description of the Test

- 1. I will give you a package and ask you to read the instructions and open and properly close the package.
- 2. I will then give you an identical package, and ask you to open and properly close it.
- 3. I may ask you to open some other types of packages.
- 4. The packages may be empty or they may contain a product.
- 5. I will ask you whether you think the child-resistant package was easy or hard to

Consent Form for Child-Resistant Package Testing

The Consumer Product Safety Commission has been using contractors to test child-resistant packages for many years with no injuries to anyone, although it is possible that a minor injury could happen.

I agree to test a child-resistant package. I understand that I can change my mind at any time. I am between the ages of 50 and 70,

inclusive.		
Birthdate		
Signature		
Date		
Zip Code		
Office Use		
Site:		
Sample Number:		
Test Number:		
Package Number:		
2. Unit-dose packages		

[Testing Organization's Letterhead]

Unit Dose Child-Resistant Package Testing

The U.S. Consumer Product Safety Commission is responsible for testing childresistant packages to make sure they protect young children from medicines and dangerous household products. With the help of people like you, manufacturers are able to improve the packages we use, keeping the contents safe from children but easier for the rest of us to open.

Effective child-resistant packages have prevented thousands of poisonings since the Poison Prevention Act was passed in 1970.

The use of child-resistant packages on prescription medicines alone may have saved the lives of over 350 children since 1974.

As part of this program, we are testing a child-resistant package to determine if it can be opened by an adult who is between 50 and 70 years of age. You may or may not be familiar with the packages we are testing. Take your time, and please do not feel that you are being tested—we are testing the package, not you.

Description of the Test

- 1. I will give you a package and ask you to read the instructions, open one unit, and remove the contents.
- 2. I will then give you an identical package, and ask you to open one unit and remove the contents.
- 3. I may ask you to open some other types of packages.
- I will ask you whether you think the child-resistant package was easy or hard to use.

Consent Form for Child-Resistant Package Testing

The Consumer Product Safety Commission has been using contractors to test child-resistant packages for many years with no injuries to anyone, although it is possible that a minor injury could happen.

I agree to test a child-resistant package. I understand that I can change my mind at any time. I am between the ages of 50 and 70, inclusive

§1700.14 [Amended]

Package Number:

5. Section 1700.14(a) introductory text is amended by inserting "meeting the requirements of § 1700.20(a)" after "is such that special packaging".

Dated: July 11, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

Appendix I—List of Relevant Documents

(This Appendix will not be printed in the Code of Federal Regulations.)

- 1. Woodson, W.E. & Conover, D.W. (1964). Human Engineering Guide for Equipment Designers. (2d. ed). Berkeley: University of California Press.
- 2. Sheffner, A. Leonard, PhD, ASTM IV A, Non-Reclosable CR pouch with internal (hidden) tear notch opening Packaging, Child and Adult Protocol Tests, Foster D. Snell, Inc, Florham Park, New Jersey 07932, December 1, 1972. (May contain confidential information.)
- 3. Breault, H.J., "Five Years with 5 Million Child-Resistant Containers," Windsor Poison

Control Center, Windsor, Ontario, Canada, Clinical Toxicology 7(1), pp. 91–95, 1974.

- 4. Sheffner, A. Leonard, PhD, ASTM IV A, Non-Reclosable CR pouch (PP/PE/F/PE) with internal (hidden) tear notch opening Packaging, Child and Adult Protocol Tests, Foster D. Snell, Inc, Florham Park, New Jersey 07932, March 10, 1975. (May contain confidential information.)
- 5. Dershewitz, R.A. & Williamson, J.W. (1977). Prevention of childhood household injuries: A controlled clinical trial. American Journal of Public Health, 67(12), 1148–1153.
- 6. Sheffner, A. Leonard, PhD, ASTM IV A, Non-Reclosable CR pouch with internal (hidden) tear notch opening Packaging, polyester/LDPE, Child Protocol Tests, Foster D. Snell, Inc, Florham Park, New Jersey 07932, January 9, 1978.
- 7. Sheffner, A. Leonard, PhD, ASTM IV A, Non-Reclosable CR pouch with internal (hidden) tear notch opening Packaging, polyester/LDPE, Child and Adult Protocol Tests, Foster D. Snell, Inc, Florham Park, New Jersey 07932, March 28, 1978.
- 8. Wilbur, C.J., "Determination of the minimum time to open and close CR packaging," CPSC, Health Sciences, January 1979.
- 9. Sherman, Dr. F.T., et al, Child-Resistant Containers for the Elderly, Journal of American Medical Association, March 9, 1979.
- 10. Howes, D.R., "Analyses of Poison Packaging Protocol Test Data," CPSC Engineering Sciences, March 1979.
- 11. Madison, R., "A Confirmation Test of a Child-Resistant Closure," CPSC, Engineering Sciences, June 1979.
- 12. Market Facts, Inc., "A Pilot Study of Effectiveness and Functionality of Child-Resistant Containers and Related User Attitudes", CPSC-C-77-0095, Market Facts, Inc., Washington, D.C., 20006, October 1979.
- 13. Associated Testing Laboratories, Inc., Wayne, New Jersey, 07470, "Child-Resistant Blister 2 x 4 tablets, Peel Back and Push Out, ASTM-VIII-D, Protocol Test Report, No. T3999–001," November 19, 1979.
- 14. Dershewitz, R.A. (1979). Will Mothers use free household safety devices? American Journal of the Diseases of Childhood, 133, 61–64
- 15. Survey of Consumers' Use of Products Regulated under the Poison Prevention Packaging Act, Chilton Research Services, May 1980.
- 16. McCormick, E.J., & Sanders, M.S. (1982). Human Factors in Engineering and Design. (Fifth Edition). New York: McGraw-Hill Book Company.
- 17. Williams, A.F. (1982). Passive and active measures for controlling disease and injury: The role of health psychologists. Health Psychology, 1(4), 399–409.
- 18. Proceedings of the Human Factors Society, 27th Annual Meeting, Norfolk VA, Volume 1, October 10–14, 1983.
- 19. Orzech, D., CPSC, "Summary of Comments Received Re: ANPR Protocol Revisions," October 14, 1983.
- 20. Spungen, H.S. and Schuirmann, D.J. "Accessibility of Tamper Resistant Packaging to the Elderly," FDA, Center for Drugs and Biologies, 1984.
- 21. Thein, W.M.A., Rogmans, W.H.J., "Testing Child-Resistance for Access by