



NATIONAL POISON PREVENTION WEEK

1-800-222-1222



Own it!

CHILD RESISTANT PACKAGING

Testing Under COVID Conditions

Lori Mitchell Dixon, PhD

March 2021



LABORATORY
ACCREDITATION
BUREAU a division of A-S-B
ACCREDITED ISO/IEC 17025

Introductions – Lori Mitchell Dixon, PhD

- President of Great Lakes Marketing
- Director of **Operation Safe Child**
- Member of ASTM, CSA and other regulatory bodies
- Chair of National Poison Prevention Week Council
- Project Director for consumer studies related to packaging
- GLM has been testing CR packages since PPPA was enacted

LDixon@GLM.com
419-534-4710

ChildResistant.com

Introductions – Jan Hepler & Deb Stout

 Jan Hepler

 Project Manager,
Operation Safe Child


 About 20 years working with
PPPA and related testing

 At your service
Jan@GLM.com
419.481.1048

 Deb Stout

 Project Manager,
Operation Safe Child

 About 15 years working with
PPPA and related testing

 At your service
Deb@GLM.com
419.481.1045

U.S. CONSUMER PRODUCT SAFETY COMMISSION



Office of Compliance

Requirements¹ under the Poison Prevention Packaging Act,
16 C.F.R. 1700

For clarification

§ 1700.15 Poison prevention packaging standards

§ 1700.20 Testing procedure for special packaging

CHILD RESISTANT PACKAGE TESTING

INFORMATION RESOURCE FOR THE TESTING, CLASSIFICATION, AND REGULATION OF CHILD RESISTANT PRODUCTS



ABOUT

ChildResistant.com

Child resistant (CR) packaging is specifically designed to help reduce the instances of accidental poisoning in children through the ingestion of prescriptions, over-the-counter (OTC) medications, pesticides, and various other household chemicals. CR packaging, also referred to as "special packaging," is required by the Poison Prevention Packaging Act (PPPA) of 1970 and regulated by the U.S. Consumer Product Safety Commission (CPSC) via the Consumer Product Safety Act (CPSA) and the Consumer Product Safety Improvement Act (CPSIA). The Environmental Protection Agency (EPA) is responsible for the regulation of economic poisons (i.e., pesticides and bait stations), which is also covered in the PPPA.

According to the PPPA, CR packaging must be designed to meet two requirements: the packaging must be significantly difficult for children under the age of 5 years to open, and must not be difficult for adults to open (the Act also allows accommodations to be made for the elderly and handicapped who might struggle with CR packaging). To ensure that

Focus for Today

- Enforcement Discretion Extension Letter
- What does it mean?
- Differences between 16CFR1700.20 and ISO standards
- Q&A



Enforcement Discretion Letter

June 25, 2020



U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

**Poison Prevention Packaging Act (PPPA) Enforcement Discretion
Testing Advisory Letter**

June 25, 2020

Dear Sir or Madam:

I am writing to announce certain enforcement discretion for packages subject to the testing requirements of the Poison Prevention Packaging Act (PPPA) and its implementing regulations, stemming from testing challenges posed by COVID-19. The Office of Compliance will adhere to this enforcement discretion for 6 months until December 25, 2020.

The PPPA requires products containing a regulated substance (listed at 16 CFR § 1700.14) to be packaged in special packaging (referred to as child-resistant and senior-friendly packaging). The packaging required by the PPPA must be designed or constructed to be significantly difficult for children under 5 years of age to open within a reasonable time, and not be difficult for normal adults to use properly.

Under the Consumer Product Safety Improvement Act of 2008 (CPSIA), the importer or the domestic party that packages a PPPA-regulated substance in special packaging must issue the general certificate of conformity (GCC) to validate that the product meets the applicable requirements of 16 CFR § 1700.15. This certification is supported by the child-resistance and senior-friendly testing data (also known as protocol data), obtained in accordance with the procedures described under 16 CFR § 1700.20.

During an open public meeting held on May 14, 2020, PPPA testing firms informed us that testing for certification to the PPPA has been halted as a result of the COVID-19 pandemic. The firms further informed us that due to public health guidance for social distancing, testing to all of the procedures described under 16 CFR § 1700.20 may not be feasible.

The full letter is available in the document section on
[ChildResistant.com/product-types-protocols-regulations/](https://www.childresistant.com/product-types-protocols-regulations/)

What is the significance of the letter?

In consideration of this information, the Office of Compliance will accept the following alternatives for 6 months, to ease the current interruption of testing and certification under the PPPA:

- Testing protocol data to the methods described under the international standards ISO 8317, ISO 14375, EN 862, CSA Z76.1 and CSA Z76.2, in lieu of the method described under 16 CFR § 1700.20;
- Transparent barriers between the tester and test subjects (children or adults), and in the cases of the child test, between children¹; and

- Provides a list of alternate test standards to 16 CFR 1700.20 testing protocol
- Modifies 16 CFR 1700.20 (sites and transparent barriers)

Excerpts
from
letter:

- Single-site child and adult testing under 16 CFR § 1700.20.²

2. The alternative site location for testing can be in lieu of a site familiar to the children. The site restrictions prohibiting 20% of children and 24% of adults being obtained from or tested at any one site will be waived; however, no more than 20% of children and 24% of adults may be from the same zip code. Testers should record the permanent zip code of the test subjects and also note whether an alternative test site was used in the testing protocol data.

What
does this
mean?

- Multiple test site restriction suspended
- Identification of alternate test site in the report
- Participant ZIP Code ensures sampling distribution

Testing protocol comparison

	16 CFR 1700.20	ISO 8317	ISO 14375
Reclosable packages	✓	✓	
Non-recloseable packages	✓		✓
Children 42-51 months	✓	✓	✓
50% male / 50% female	✓	✓	✓
Test site requirements	→ ✓	✓*	
Tester requirements	✓		
Teeth prompt used	✓		
Sequential panel starting at 50	✓		
Sequential panel starting at 30		✓	✓

*Only requires 3 test sites rather than 20% or less of the panel being tested at one site.

A more extensive comparison chart of international standards is available in the document section on ChildResistant.com/product-types-protocols-regulations/



Standardized Process

- “Please try to open this for me.”
- After 5 minutes, ask them to stop working on the package
- “**Watch me open my package.**”
- Demonstrate (visually only) how to open the package
- **“Now you try to open your package. You can use your teeth if you want to.”**
- Time the second 5-minute period
- Give them *grandma lecture*

Use of Teeth by Age

Use Teeth Before and After Demonstration	42 – 44 months (a)	45 – 48 months (b)	49 – 51 months (c)
Teeth Used before Demo	4.8% (bc)	5.6% (ac)	7.1% (ab)
Teeth Used after Demo	39.3% (bc)	44.9% (ac)	48.1% (ab)

(abc) Statistical difference at 90% level of confidence
Based on completed (and passed) tests

Excerpt
from
letter:

For regulated products in special packaging and certified using any of the alternatives outlined in our enforcement discretion, the General Certificate of Conformity (GCC) and testing protocol data must be submitted by the importer or domestic manufacturer to the Office of Compliance, by emailing: RegulatedCMT@cpsc.gov, before distribution into commerce. All other requirements under 16 CFR § 1700.20 remain in full force and effect.

What
does this
mean?

If the test is conducted during the discretionary enforcement period:
→ the test report must be submitted to RegulatedCMT@cpsc.gov by the importer or manufacturer.

GLM Reports

All GLM reports produced during the enforcement discretion include:

A General Certificate of Compliance template



A cover letter stating the standard used for the test/next steps.

A copy of both CPSC letters.



The protocol test summary.



Original data sheets



Enforcement Discretion Extension Letter

November 12,
2020



U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

**Poison Prevention Packaging Act (PPPA) Enforcement Discretion
Extension Letter**

November 12, 2020

Dear Sir or Madam:

Given continued testing challenges related to Covid-19, the Office of Compliance and Field Operations is extending, through June 25, 2021, the enforcement discretion for packages subject to the testing requirements of the Poison Prevention Packaging Act (PPPA), described in my June 25, 2020 [letter](#).

In addition, we are expanding the enforcement discretion to accept the use of the adult-resecuring data (16 CFR § 1700.20(d)(2)) as the basis for determining whether a package meets the child-resistant requirements to reduce the total number of children needed for testing. Answers to potential questions regarding application of the adult-resecuring test for determining child-resistance acceptance, as well as other aspects of the enforcement discretion, are attached.

For regulated products in special packaging and certified using any of the alternatives outlined in our enforcement discretion, the General Certificate of Conformity (GCC) and testing protocol data must be submitted by the importer or domestic manufacturer to the Office of Compliance, by emailing: RegulatedCMT@cpsc.gov, before distribution into commerce. All other requirements under 16 CFR § 1700.20 remain in full force and effect.

Again, this enforcement discretion will remain in effect until June 25, 2021. Please direct any questions to: RegulatedCMT@cpsc.gov. Thank you for your cooperation.

Sincerely,

A handwritten signature in cursive script that reads "Robert Kaye".

Robert S. Kaye
Director

The full letter is available in the document section on
[ChildResistant.com/product-types-protocols-regulations/](https://www.childresistant.com/product-types-protocols-regulations/)

What does the extension mean?

Again, this enforcement discretion will remain in effect until June 25, 2021. Please direct any questions to: RegulatedCMT@cpsc.gov. Thank you for your cooperation.

• Timeline

- **CURRENT:** Until June 25, 2021
- **CURRENT THINKING:** Testing should be finished “close to June 25”
- **POTENTIAL:** This will be extended; CPSC is asking for feedback

• Clarifications

Excerpt
from
letter:

Testing to 16 CFR § 1700.20

Question: Does the test to 16 CFR § 1700.20 expire?

Answer: There is no expiration date when testing to 16 CFR § 1700.20, and there is no requirement to retest, as long as the tests adequately reflect the current package and substance contained in the package. If there is a material change in the packaging or substance within the package, or there is a change in the manufacturing process, then we recommend retesting to ensure that the package continues to meet the PPPA requirements.

What
does this
mean?

- There is no expiration date for packages tested during the enforcement period as long as the package remains the same.

Clarifying Test Acceptance Dates

Testing During the Enforcement Discretion Period

Question: If testing for certification to the PPPA was conducted to the accepted alternative method(s) of § 1700.20, or to an international standard **during** the enforcement discretion period, does the package need to be retested after the enforcement discretion period ends?

Answer: No, but the GCC and testing protocol data must be submitted by email. (RegulatedCMT@cpsc.gov) before distribution into commerce. (*See Figure 1*)

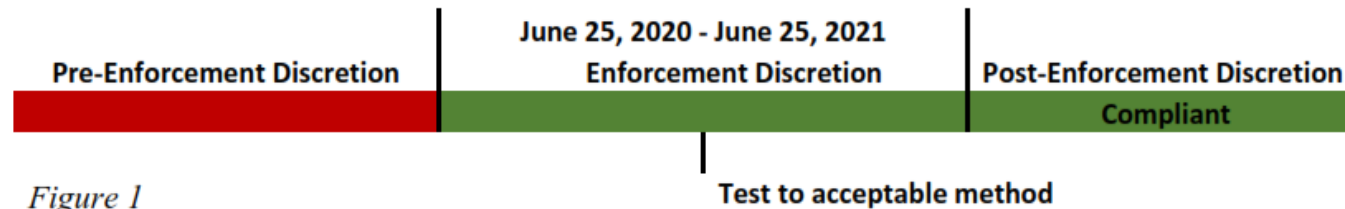


Figure 1

Excerpt
from
letter:

- Packages tested to alternate standards during the enforcement discretion **do not need to be retested to 16 CFR 1700.**
- There is **no expiration date** for packages tested during the enforcement period.

Clarifying Non-Compliant Testing

Testing Prior to the Enforcement Discretion Period

Question: If testing was conducted to an international standard **prior to** the enforcement discretion period, does the package need to be retested before the enforcement discretion period ends?

Answer: Yes. Testing to a standard other than 16 CFR § 1700.20 was not accepted for certification to the PPPA prior to the enforcement discretion period. Although it will be accepted as a basis for certification during the enforcement discretion period, it will not be accepted after June 25, 2021 (*See Figure 2*). The package shall be retested to § 1700.20, the accepted alternative method(s) of § 1700.20, or to an international standard during the enforcement discretion period to be accepted after June 25, 2021 (*See Figure 3*).



Figure 2

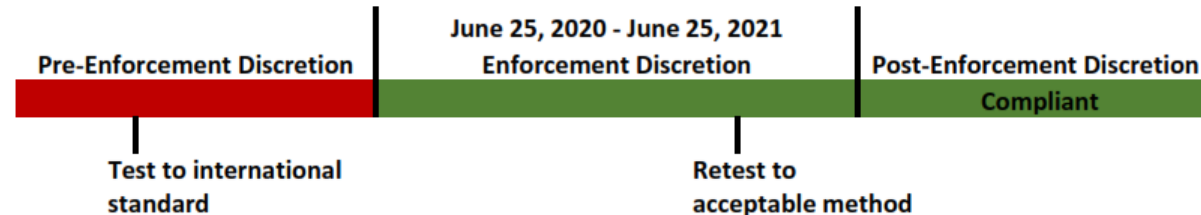


Figure 3

Packages tested to alternate standards prior to the enforcement period are not compliant.

Excerpt
from
letter:

In addition, we are expanding the enforcement discretion to accept the use of the adult-resecuring data (16 CFR § 1700.20(d)(2)) as the basis for determining whether a package meets the child-resistant requirements to reduce the total number of children needed for testing. Answers to potential questions regarding application of the adult-resecuring test for determining child-resistance acceptance, as well as other aspects of the enforcement discretion, are attached.



- Prior to this enforcement discretion:
 - Resecure = SAUE + Child Panel
 - Adult-tested bottles were tested by children to ensure the cap was put on properly.
 - A supporting child panel was also conducted.
- During enforcement discretion:
 - Testing to ISO 8317 does not require a resecure test. The packages closed by seniors are “verified” by the tester.
 - The child panel is a traditional ISO child panel.

Excerpt
from
letter:

Adult-Resecuring Test

Question: When should the adult-resecuring test be recommended?

Answer: When an objective determination (*e.g.* visual or mechanical) cannot be made establishing that a reclosable package is properly resecured after the senior-adult test (16 CFR § 1700.20(a)(3)), or the younger-adult test (16 CFR § 1700.20(a)(4)), then we recommend that the package be retested with children, following the adult-resecuring procedure set forth in 16 CFR § 1700.20(d)(2).



- Same as before...

Excerpt
from
letter:

Question: During the enforcement discretion period, can the criteria from the adult-resecurer test be used to determine whether the package meets the child-resistant requirements instead of conducting a separate child-test procedure (16 CFR § 1700.20(a)(2))?

Answer: Yes. To reduce the total number of children required to test the package, the Office of Compliance will accept an adult-resecurer test as the basis for determining whether the packaging meets the child-resistant packaging requirements during the enforcement discretion period. The procedures of the adult-resecurer test state that children are to be tested according to the child-test procedures.

What does this mean?

- If testing is conducted to 16 CFR, the SAUE test is calculated as usual.
- An additional supporting child panel is not needed.
 - The children tested as part of the SAUE are used to determine the child panel passing rates.

Steps to prepare for testing

Initial
call

Review
Set up form

Assess
pkg

Package preparation
Testers briefed

Testing
begins

Update
Monitor
Report



Thank you for having Great Lakes Marketing conduct your child resistant package protocol testing. We are accredited to test child resistant packages (ISO 17025) according to 16CFR1700 (the US standard) and all relevant international standards. We are also an accredited certifying body (ISO 17065). This form is vital for us to document the test procedures in full, so the final report meets the requirements of the regulation. Please complete each box. If you have questions, please email: SafeChild@GLM.com

Contact for updates & report:	Name/Title:
	Company:
	Email Address/Phone:

Company address of record:	Address: City/State/Zip:
Location where packages made:	Address: City/State/Zip: <input type="checkbox"/> ✓ if same as above
Location where packages were prepared for testing:	Address: City/State/Zip: <input type="checkbox"/> ✓ if same as above
Describe all procedures for preparing the test packages (including if the packages were cycled*):	*Cycled means opened/closed to simulate expected lifetime use.
Purchase Order #:	

PACKAGE TYPE (fill in name and check box below)	
Package Name:	(This is the name that will be used in the report; this must be filled in.)
<input type="checkbox"/> Re-closeable (continuous thread cap) ➡	The report must state the torque value if the caps are on the container. Or, we will apply the caps at the expected torque level. Actual or expected torque value: _____ If caps were applied, date/time last cap applied: _____
<input type="checkbox"/> Cap and Container ➡	Any cap/bottle package that is not torque dependent.
<input type="checkbox"/> Unit Dose ➡	The report must state the failure level (the number of units that could cause harm/serious injury to a child). Failure level: _____ Number of pills/tablets on each card: _____
<input type="checkbox"/> Other ➡	(i.e., pouch, box, etc.)

FORM 50.4 – 3/12/20

TESTING THE EFFECTIVENESS OF CHILD-RESISTANT PACKAGING SINCE 1970

Page 1 of 2



Contact info



Test type & details

The full form is available in the document section on ChildResistant.com/ready-to-start/

We test according to the US standards (16CFR1700). If you need to meet other requirements, please check the box (we are accredited to test to all standards).

<input type="checkbox"/> CSA (Canadian)	<input type="checkbox"/> ISO (International)
<input type="checkbox"/> EPA (US)	<input type="checkbox"/> ASTM2517 (Portable Fuel Containers)
<input type="checkbox"/> EN (European)	

The regulations require that the package definition be as detailed as possible. Please complete as much of this information as possible. This information will be included in the report. Complete the information for each component of your package.

COMPONENT A (i.e., bottle, container, card, etc.)		COMPONENT B (as needed) (i.e., cap, attached outer box, etc.)	
Description:		Description:	
Manufacturer:		Manufacturer:	
Material & Color:		Material & Color:	
Code Number:		Code Number:	
Lot Number:		Lot Number:	
Sealing Method/Temp:		Sealing Method/Temp:	
Drawing/Ref Numbers/Other:		Closure Liner Material:	
		Drawing/Ref Numbers/Other:	

Your checklist of items to send to Great Lakes Marketing: (Great Lakes Marketing, 3361 Executive Parkway, Suite 200, Toledo, Ohio 43606)

- ☐ This 2-page form (email this to us and enclose in the box if you can)
- ☐ Packages (carefully packed so there is no damage in transit)
- ☐ A memo detailing the placebo contents (if a placebo is included) (due to allergies food should not be used)
- ☐ Opening directions (that match the final directions) (if not on the package they can be on a separate page using the same size, font, etc.)
- ☐ The package must retain CR properties for the expected life of the package. You will need documentation that this requirement has been met (or packages can be cycled).

You will receive:

- ☐ An email when your packages arrive
- ☐ An email confirming we have everything we need and can start testing
- ☐ Periodic updates during the testing (about 2 to 3 times a week)
- ☐ A full report (hard copy) and PDF on a flash drive
- ☐ A Certificate of Conformity template (that you may choose to publish on your company website)

If you would like your samples returned, please provide your FedEx or UPS #, otherwise your samples will be destroyed:

FedEx #: _____ UPS #: _____

If you would like your package certified (per ISO 17065), please check this box ☐ and we will send the Certification Packet. Certification offers several benefits, such as a seal to place on your marketing materials, a listing on ChildResistant.com, archival services, etc. Certification is an additional fee.

Client Signature: _____ (digital accepted)	Date: _____
Reviewer Signature: _____	Date: _____

➔ Package identification

➔ Checklist

➔ Process

The full form is available in the document section on ChildResistant.com/ready-to-start/

Comparison Chart



Child Resistant Packaging Standards

This chart shows variances among standards for child resistant packaging. The variances listed below are based on the Interpretation of Great Lakes Marketing. If no variances exist between 16CFR1700; follow 16CFR1700. It is always wise to check with the authorizing agency if questions arise or the package is a new design. These notes are for child resistant protocol testing only. Several other standards apply for child resistant packages (i.e., durability, markings, leakage, compatibility, etc.).



Name	16 CFR 1700	CSA Z76.1 - 16	40 CFR 157	ASTM F2517 - 17	ISO 8317-15	ISO 14375:2018	EN 862:2006-02
Title	Poison Prevention Packaging Act (PPPA) of 1970 Regulations.	Reclosable child-resistant packages.	Requirements for child-resistant packaging of pesticide products and devices.	Standard Specification for Determination of Child Resistance of Portable Fuel Containers for Consumer Use.	Child-resistant packaging—requirements and testing procedures for redosable packages.	Child-resistant non-redosable packaging for pharmaceutical products.	Requirements and testing procedures for non-redosable packages for non-pharmaceutical products.
Related Organization	Consumer Product Safety Commission (CPSC) (as given authority by the PPPA).	Canadian Standards Association (CSA)	United States Environmental Protection Agency (EPA)	Association for Standards and Testing Materials (ASTM)	International Standards Organization (ISO/IEC)	International Standards Organization (ISO)	European Community for Standardization (CEN)
Regulates	Packaging for any substance deemed hazardous by CPSC (see 1700.14 for list) sold for use in or around the household.	Reclosable child-resistant packages (this does not apply to non-redosable packages).	Established under the authority of FIFRA section 25(a)(1)(3) which authorizes standards for package, container, or wrapping for pesticide or device.	Container includes the receptacle, spout, retrofit spouts, caps and other closure mechanisms.	Reclosable packages designated as child resistant.	Non-redosable packaging designated as child resistant.	Child-resistant, non-redosable, non-pharmaceutical packaging.
Necessary Client Prep and Package Definition	1700.1(b)(3) Immediate package is tested. 1700.20 (A)(i) Any tamper-resistant feature of the package shall be removed prior to testing unless it is part of the child-resistant design. 1700.20(b) For redosable packages, the caps are applied using the online torque value at least 72 hours prior to testing. 1700.20(a) Redosable packages shall be opened and properly resecured one time (or more) by tester or <u>other</u> adult prior to child test.	8.1.1 Non immediate packaging is removed. 8.1.4. f) tamper evident materials are removed. 8.1.4 e) All packages shall contain a placebo.	157.21 Immediate container or wrapping, including any attached closures. 157.27 Packaging for each unit or for the outer retail container which houses the units.	3.1. Containers and closures must meet several other safety standards/requirements. 3.1.3.1 [Subjected to] 8°F (-17.8° C) for 8 hrs. 3.1.3.2 [Subjected to] 140°F (60° C) for 8 hrs. 3.1.3.3 Opening and closing of each closure for 250 cycles. 3.1.4 Containers shall be inverted and inspected visually to determine any leakage.	3.1.1 Only new packages should be tested; each child is given a new package to test. 4.3 Packages are opened and closed once before testing. All tamper evident material is removed. 4.3 Placebo is to be used; quantities are specified.	5.2 Packages for the child panel test shall be unprinted. Each sample package shall be checked for integrity before the test is conducted. There shall be at least 10 unit doses for each child and adult.	4.2 Packages for the child panel test shall be unprinted. Each sample package shall be checked for integrity before the test.
Child Panel Composition/ Standards	1700.20 • s20% from any site • 30% 42-44 months; 40% 45-48 months; 30% 49-51 months • 50% male/female ratio within 10% in each of the three age groups. • s30% tested by any one tester • Maximum of two packages tested per child; must be of different ASTM types	8.3.2 For 200 child panel: • 40 ± 4 children from each two-month age (42-43, 44-45 months, etc.) • s60% of any age group from the same sex 9.1.2 For sequential panel (for child panel only that is not part of a resealing test): A minimum of 30 children using grid shown in Figure 2.	157.32 References testing protocol of 16CFR1700.20.	4.5.1 Central location testing is allowed. 4.2.4 Same as 16CFR1700.20 4.6.8. Child is told: "Please try to open this for me or to get the liquid out."	3.3.3.2: For sequential panels, as few as 30 children can be tested; use Figures 2 and 3. 4.4.2 If a child is used on more than one test panel, it is desirable that there should be at least one week between the tests. 4.4.3 Test sites can be any location where child is released; a minimum of 3 sites is needed.	5.3.2.1 If a child is used for more than one test there shall be at least 4 weeks between tests. Parental or guardian consent shall be obtained before the child is used as part of the test group. 5.3.2.2 Test personnel should visit the site beforehand and become known to the children. A.4 Exclude children involved in a reported poisoning accident.	4.3.2.1 If a child is used for more than one test there shall be at least 4 weeks between tests. Parental or guardian consent shall be obtained before the child is used as a part of the test group. 4.3.2.2 Test personnel should visit the site beforehand and become known to the children. 4.3.2.3 Exclude children involved in a reported poisoning accident.
Sequential Testing	1700.20(a)(ii) Use Figure 1; minimum of 50 children.	9.1.2 Use Figures 2 & 3; minimum of 30 children	Using Figure 1; minimum of 50 children.	4.4 Use Figure 1; minimum of 50 children.	3.3.3.2 Use Figures 2 & 3; minimum of 30 children.	5.4.1.1 Use Figures 2 & 3; minimum of 30 children.	4.4.1.2 Using Figures 2 & 3; minimum of 30 children.

ChildResistant.com

Or ask me for one and I will send it to you.

Certification Body





NATIONAL
POISON
PREVENTION
WEEK

Stay Healthy

*Share the
messages of
National Poison
Prevention
Week*

Questions/Comments?

LORI MITCHELL DIXON, PHD

419.534.4710

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