



United States

**Consumer Product Safety Commission**

# **Poison Prevention Packaging: A Guide for Healthcare Professionals**

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*This document was prepared by CPSC staff.  
It has not been reviewed or approved by,  
and may not necessarily reflect the views of,  
the Commission.*



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## Preface

The U.S. Consumer Product Safety Commission (CPSC) administers the Poison Prevention Packaging Act of 1970 (PPPA), 15 U.S.C. §§ 1471-1477. The PPPA requires special (child-resistant and adult-friendly) packaging of a wide range of hazardous household substances, including oral prescription and over-the-counter drugs. Healthcare professionals are more directly involved with the regulations dealing with drug products than household chemical products.

Over the years that the regulations have been in effect, there have been remarkable declines in reported deaths from ingestions by children of toxic household substances, including medications. Despite this reduction in deaths, many children are poisoned, or have “near-misses,” with medicines and household chemicals each year. Using data from the National Electronic Injury Surveillance System (NEISS), an estimated 58,200 children under 5 years of age were treated for poisonings in hospital emergency rooms in the United States in 2020.<sup>1</sup> The American Association of Poison Control Centers (AAPCC) reported 2,128,198 calls (not limited to drug products) related to human exposure in 2020, 42 percent of which involved exposure to children under 5 years of age.<sup>2</sup>

Some of the reasons for the continuing ingestions, besides exposure issues, are availability of conventional (non-special) packaging, on request, for prescription medication; availability of one conventional packaging size of over-the-counter medications (a.k.a. noncomplying packaging); inadequate quality control by manufacturers, leading to defective closures; not using special packaging in the home (leaving the cap off or unsecured, transferring the contents to conventional packaging); and violations of the law by the pharmacist and/or the dispensing physician.

This guidance is designed to educate pharmacists, physicians, and other healthcare professionals about their responsibilities under the PPPA. It is intended to be incorporated into the ongoing curricula of medical, pharmacy, nurse practitioner, and physician assistant programs and schools, with the hope that healthcare professionals will become more aware of their responsibilities under the law. By learning the advantages of special packaging, and by making a concerted effort to promote its use, healthcare professionals will help to further decrease ingestions by young children.

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<sup>1</sup> [https://www.cpsc.gov/s3fs-public/AnnualReportonPediatricPoisoningFatalitiesandInjuries\\_January2022.pdf?VersionId=k06y6jg2vZJgMHWbSZ1q.k0paJhv\\_dz](https://www.cpsc.gov/s3fs-public/AnnualReportonPediatricPoisoningFatalitiesandInjuries_January2022.pdf?VersionId=k06y6jg2vZJgMHWbSZ1q.k0paJhv_dz)

<sup>2</sup> AAPCC “2020 Data Snapshot” <https://piper.filecamp.com/uniq/HuSXBWJJYHBW7mN2.pdf>.

# Part 1: The History of Poison Prevention

## Background

“A child learns by doing. He gains experience by investigating the world around him. For his experiences to be constructive, they must be conducted in an environment where hazards are kept to a minimum.”<sup>3</sup>

Before the PPPA was enacted in 1970, poisonings by common household substances, including medicines, had long been considered by pediatricians to be the leading cause of injuries among children under 5 years of age. At one point, state death certificates reported about 500 fatalities a year in children under 5, due to poisoning caused by unintentional ingestion of drugs and household products.

As a result of the many injuries, individual poison control centers were established within their respective communities, to provide specialized diagnoses and treatments for poisonings. The first poison control center started in Chicago in 1953. As these centers proliferated, the need for a coordinating body became apparent, to avoid duplicative work. In 1957, the National Clearinghouse for Poison Control Centers (Clearinghouse) was established with the mandate to collect data from the centers and provide them with diagnostic and therapeutic information on the myriad household products involved in childhood poisonings.<sup>4</sup> The Clearinghouse became the largest repository in the world of reports of poisonings. These reports became the primary source of data to evaluate the incidence of childhood poisoning. The Clearinghouse data collection ended in 1984. Currently, poisoning cases reported to poison control centers are documented in the Toxic Exposure Surveillance System (TESS), maintained by the AAPCC. The NEISS, run by CPSC, is a source of national estimates of poisoning cases treated in hospital emergency rooms, and it provides a follow-up mechanism when additional details about a particular drug or type of incident are needed.

A review of reports from poison control centers revealed a direct relationship between the stage of a child's development and the type of substance being ingested.<sup>5</sup> For example, youngsters still in the crawling stage were much more apt to get into products stored on the floor of the bathroom or the cabinet below the kitchen sink (soaps and detergents, drain, and bowl cleaners). Toddlers were able to reach products left on low-lying tables (uncapped bottles of furniture polish, for example). By the time youngsters were able to climb, they were reaching into the medicine cabinet.

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<sup>3</sup> Eason, L.A. “The Evolutions and Interest Conflicts Involved in the Poison Prevention Packaging Act of 1970,” Unpublished, Auburn University, Alabama, 8/25/72, p. 3.

<sup>4</sup> Verhulst, H.L. “National Clearinghouse for Poison Control Centers,” *Military Medicine*, 1(122): 321, 1958.

<sup>5</sup> Cann, Howard M., M.D. Iskrant, Albert, P., and Neyman, Dorothy, S. “Epidemiological Aspects of Poisoning Accidents,” *American Journal of Public Health*, 50(12): December 1960, p. 1922.

In 1970, Congress passed, and the President signed, Public Law No. 91-601, the PPPA. The legislation formed the basis for a new attack on the problem of unintentional poisoning among young children.

The U.S. Food and Drug Administration (FDA) was responsible for enforcing the PPPA until 1973, when jurisdiction was transferred to the newly formed CPSC.<sup>6</sup> The PPPA gives CPSC the authority to require “special packaging” of certain household substances to protect children from serious injury or illness.

The PPPA defines “special packaging” as “packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.”<sup>7</sup>

Human performance tests were developed to measure child resistance and adult friendliness. Children aged 42 months to 51 months were chosen as the test subjects. The test method was developed to try to mimic the situation found at home. The test involved giving packages to pairs of children. The children were given 5 minutes to try to open the package. If they did not open their package within that time, the children were given a single visual demonstration and then given another 5 minutes to attempt to open the package. The package was considered to be child resistant if not more than 20 percent of 200 children tested could open the package.<sup>8</sup>

The packages also had to be opened and properly closed by adults. Adults aged 18 years to 45 years were chosen as the test subjects. The adults had a 5-minute period to open and properly close the package. The package was considered to be adult friendly if at least 90 percent of 100 adults tested could open and close the package.

## Improving the Packaging

The test methods and standards described above were adopted in the early 1970s. CPSC enforced these standards to make sure that special packaging in the market complied. Packaged products that did not meet the standards were recalled.

CPSC staff continued to monitor ingestions. In 1986, CPSC conducted an ingestion study with the AAPCC.<sup>9</sup> The results indicated that children were being poisoned by drugs that belonged to their grandparents. Many of these incidents occurred because special packaging was not being used; the closures were not resecured (closed loosely), or the closures were left off. In other cases, the drugs were not in special packaging at all.

CPSC tested the packaging with adults over a wide range of ages up to 75 years. Many adults, especially seniors, could not open special packaging. Children were poisoned because seniors

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<sup>6</sup> 15 U.S.C. § 2053.

<sup>7</sup> 15 U.S.C. § 1471(4).

<sup>8</sup> 38 FR 21247 (Aug. 7, 1973).

<sup>9</sup> Jacobson, B., Rock, A., Cohn, M., and Litovitz, T. “Accidental Ingestions of Oral Prescription Drugs: A Multicenter Survey,” *American Journal of Public Health*, 79:853-856, 1989.

could not use the packaging. CPSC worked to revise the adult test methods to increase the age of adults tested. In 1995, CPSC issued new requirements that amended the test procedures.<sup>10</sup> Adults aged 50 years to 70 years old are now tested to measure adult-use effectiveness for most packages. In addition, the child test was revised to use panels of 50 children; this greatly reduces the number of children who need to be tested (effectiveness for testing less than 200 children is greater than 85% pre-demonstration and 80% post-demonstration). These changes became effective in January 1998, and packages became easier for seniors to use properly while maintaining their child resistance.

## Success

CPSC analyzed child-fatality data for unintentional ingestions of oral prescription medicines during the period 1964 through 1992. The results of the analysis showed that the death rates for ingesting oral prescription medicines declined even after changes in the consumption of the medications over time and the long-term decline in the overall unintentional death rate of children from all causes.<sup>11</sup>

The study showed that special packaging reduced the oral prescription medicine-related death rate by up to 1.4 deaths per million children under age 5. This represents a reduction in the rate of fatalities of up to 45 percent from levels that would have been projected in the absence of special-packaging requirements, and it equates to about 24 fewer child deaths annually.<sup>12</sup>

A similar study of the effectiveness of special packaging of aspirin estimated that special packaging reduced the aspirin-related mortality rate by 34 percent. This equates to about 90 fewer child deaths from aspirin during the 1973-1990 study period.<sup>13</sup>

When combining the statistics for aspirin and prescription drugs, CPSC staff estimated that special packaging saved the lives of more than 900 children since the requirements went into effect in the early 1970s. This estimate relates to aspirin and oral prescription medicines only and does not include additional lives that may have been saved by special packaging on other products.

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<sup>10</sup> 60 FR 37710 (July 21, 1995).

<sup>11</sup> Rodgers, G. "The Safety Effects of Child-Resistant Packaging for Oral Prescription Drugs," *Two Decades of Experience*, JAMA 275:1661-1665, 1996.

<sup>12</sup> Rodgers, G. "Let's Welcome a New Generation of Child-Resistant Packaging," *Contemporary Pediatrics*, 1997 p. 57-72.

<sup>13</sup> Rodgers, G., "The Effectiveness of Child-Resistant Packaging for Aspirin," *Arch Pediatr Adolesc Med* 156:929-933, 2002.

## Part 2: Substances Covered by the Regulation

### Background

The PPPA gives the Commission the authority to require special packaging of certain household substances to protect children. A “household substance” is defined as any substance that is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and is:

- A hazardous substance as defined by Federal Hazardous Substances Act;
- A food, drug or cosmetic as defined by the Federal Food, Drug and Cosmetic Act; or
- A substance intended for use as fuel (for heating, cooking, or refrigeration system of a house) when stored in a portable container.

Section 3 of the PPPA details the findings that the Commission must make prior to promulgating a special packaging standard. The Commission may require special packaging of a household substance if it finds that:

1. the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and
2. the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.

In establishing a standard, the Commission also considers:

1. the reasonableness of such standard;
2. available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;
3. the manufacturing practices of industries affected by the PPPA; and,
4. the nature and use of the household substance.

The responsibility for administration and enforcement of special packaging for pesticides (including cleaning products that make antimicrobial claims) lies with the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Notably, the same test methods for determining whether a package is child resistant and senior friendly apply to pesticides because the FIFRA was amended to recognize packaging and labeling violations consistent with the PPPA.<sup>14</sup>

### Special Packaging Requirements

There are four provisions of special packaging, as listed in [16 CFR § 1700.15](#). Applicability of each requirement is listed under each regulated substance in [16 CFR § 1700.14\(a\)](#). The four provisions are as follows:

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<sup>14</sup> 7 U.S.C. § 136w(c)(3).



- 1) General requirements:  
The closure must continue to function for the lifetime of the product. In addition, the introduced substance must not interfere with the closure.
- 2) Effective specifications:  
The package must have a child-resistant effectiveness of at least 85% before demonstration and at least 80% after demonstration. The package must also have a senior-friendly effectiveness of at least 90%.
- 3) Reuse of special packaging:  
Package cannot be reused.
- 4) Restricted flow:  
The package must not allow more than 2 mL of liquid to be dispensed at a time.

### List of Regulated Substances

In the years since enactment of the PPPA, many substances have been added to the list of regulated substances. Below is a list of substances that require special packaging as of 2012. There may be prerequisites or exemptions specific to each substance. Because the list is subject to updating, you should always refer to [16 CFR § 1700.14\(a\)](#) for the most current list.

- 1) Aspirin (oral dose)
- 2) Furniture polish
- 3) Methyl salicylate (liquid)
- 4) Controlled drugs (oral dose) per Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. § 801 *et seq.*)
- 5) Sodium and/or potassium hydroxide
- 6) Turpentine (liquid)
- 7) Kindling and/or illuminating preparations (liquid)
- 8) Methyl alcohol (liquid)
- 9) Sulfuric acid
- 10) Prescription drugs (oral dose)
- 11) Ethylene glycol (liquid)
- 12) Iron-containing drugs
- 13) Dietary supplements containing iron
- 14) Solvents for paint or other similar surface-coating material (liquid)
- 15) Acetaminophen (oral dose)
- 16) Diphenhydramine (oral dose)
- 17) Glue removers containing acetonitrile (liquid)
- 18) Permanent wave neutralizers containing sodium or potassium bromate (liquid)
- 19) Ibuprofen (oral dose)
- 20) Loperamide (oral dose)
- 21) Mouthwash (containing ethanol)
- 22) Lidocaine
- 23) Dibucaine
- 24) Naproxen
- 25) Ketoprofen



- 26) Fluoride
- 27) Minoxidil
- 28) Methacrylic Acid (liquid)
- 29) Over-the-counter (OTC) drug products (oral dose)
- 30) Hazardous substances containing low-viscosity hydrocarbons (liquid)
- 31) Drugs and cosmetics containing low-viscosity hydrocarbons (liquid)
- 32) Imidazolines

## Applicators

Some substances regulated under the PPPA are sold with applicators (e.g., droppers or spray pumps) that are intended to replace the original closure. The PPPA requires that regulated substances comply with the requirements of the PPPA for the life of the product. Thus, products that come packaged with applicators must continue to meet the special packaging requirements when the applicators provided are intended or able to replace the original closure.<sup>15</sup>

## Drug Samples and “Starter Kits”

Oral prescription drug samples and “starter kits” dispensed by the prescribing practitioners require special packaging; however, CPSC’s position is that manufacturers are not responsible for the special packaging of these products, because they are distributed by a licensed medical practitioner, who has the authority to specify noncomplying packaging for their patients. Regardless of the type of packaging supplied to the practitioner by the manufacturer, the PPPA establishes that the dispensing practitioner is responsible for ensuring the special packaging requirements are met, unless the practitioner decides that special packaging is not appropriate. The intent of 15 U.S.C. § 1473(b), which allows medical practitioners to order that prescribed substances subject to PPPA requirements can be dispensed in conventional packaging, is to allow practitioners to see that persons, such as the elderly or people with disabilities who struggle with opening special packaging, can still access household substances they may need (such as OTC pain medication).<sup>16</sup> This is not the case for oral prescription drugs, including samples, that are dispensed by pharmacists, because pharmacists do not have the authority to specify that prescriptions be dispensed in non-complying packaging.

## Drugs Switched from Rx to OTC Status

Diphenhydramine, ibuprofen, loperamide, naproxen, and ketoprofen are drugs that were originally available by prescription. FDA allowed OTC sale of certain formulations of these drugs. When these drugs were granted OTC status, they were no longer required to be packaged in special packaging under the oral prescription drug rule. CPSC initiated separate rulemaking activity to require special packaging of each drug. In 2001, CPSC issued a rule to require special packaging of oral prescription drugs that are granted OTC status by FDA based on an application submitted on or after January 29, 2002.<sup>17</sup> This means that special packaging

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<sup>15</sup> 63 FR 63602 (November 16, 1998).

<sup>16</sup> 49 FR 8008 (March 5, 1984).

<sup>17</sup> 66 FR 40111 (August 2, 2001).

continues to be required for these products when they are more readily available to the public. Separate rulemakings (such as those for diphenhydramine, ibuprofen, loperamide, naproxen, and ketoprofen) will be unnecessary in the future for these types of drugs.

A list of drugs that switched from Rx to OTC can be found on FDA's website at: [www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/prescription-over-counter-otc-switch-list](http://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/prescription-over-counter-otc-switch-list). Note that applicability of any special packaging requirement under the PPPA depends on the active ingredient, not any brand name or formulation.

## Exceptions and Exemptions

There are several situations when special packaging is not required.

Congress had concerns about the ability of elderly or people with disabilities to access regulated substances in special packaging; therefore, the PPPA contains provisions to facilitate access of products by these special populations. Section 4(a) of the PPPA allows for noncomplying packages of regulated substances (except prescription drugs) in a single size to facilitate access to regulated substances by the elderly or people with disabilities.<sup>18</sup> A manufacturer or packager may package PPPA-regulated substances in noncomplying packaging of a single size provided that:

1. The substance is provided in other popular sizes; and
2. The principal display panel of the package (both immediate and any outer container) bears the statement "This Package for Households Without Young Children" (or "Package Not Child-Resistant" for small packages).

This allowance is specific to dose (e.g., 81mg vs 100 mg) and physical characteristics (e.g., tablet vs. gel cap); firms may use a noncomplying package for each formulation and dose type if they are also sold in other popular sizes of each formulation and/or dose type and labeled accordingly. There is one exception to the noncomplying package exemption: under [16 CFR § 1500.17\(a\)\(4\)](#), household products containing more than 10 percent sodium/potassium hydroxide are considered to be banned hazardous substances unless in special packaging.

Section 4(b) of the PPPA addresses the need for facilitating access to prescription drugs by elderly or people with disabilities who have difficulty using special packaging:

"In the case of a household substance which is subject to such a [PPPA] standard and which is dispensed pursuant to an order of a physician, dentist, or other licensed medical practitioner authorized to prescribe, such substance may be dispensed in noncomplying packages only when directed in such order or when requested by the purchaser."<sup>19</sup>

Essentially, section 4(b) of the PPPA allows for prescription drugs to be dispensed in conventional packaging at the explicit request of the doctor or the patient.

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<sup>18</sup> 15 U.S.C. § 1473(a), codified at 16 CFR § 1700.5.

<sup>19</sup> 15 U.S.C. § 1473(b).

In [16 CFR § 1701.3](#), the Commission has indicated that substances packaged in containers with a capacity of 5 gallons or more generally would not be considered a “household substance” and, therefore, would not require special packaging.

In addition to the scenarios described above, [16 CFR part 1702](#) outlines a procedure whereby the Commission may grant exemptions from special packaging requirements in response to a petition. Upon grant of a petition, a proposed amendment to the listing of regulated substances at [16 CFR § 1700.14\(a\)](#) would be published in the *Federal Register*.

### Updated Guidance for Institutional Use

CPSC has issued updated guidance clarifying its stance on “institutional use” products.<sup>20</sup> CPSC does not recognize a blanket “institutional use” exception. Products that meet the definition of a “household substance” under the PPPA must be in special packaging regardless of how the product is labeled. Even substances intended for institutional use only, and labeled as such, must still use special packaging unless it meets one of the recognized limited exceptions.

CPSC staff recognizes that substances subject to the PPPA are also used in commercial and institutional settings, where the risk to children is diminished. Accordingly, when determining whether to seek corrective action for noncompliant products intended to be used in commercial and institutional settings, CPSC staff will consider various factors, including:

- how and where the product is advertised, marketed, sold, labeled, and distributed;
- the nature and extent of a firm’s oversight of its distribution chain;
- the packaging configuration, type, and size;
- whether the ancillary instructions provided on the package [such as for storage, handling, or use] are intended for consumers; and
- product reviews and other evidence demonstrating the nature and extent of consumer use.

These factors are not exhaustive. CPSC staff recognizes that additional changes in the marketplace may dictate other factors for consideration.

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<sup>20</sup> [www.cpsc.gov/s3fs-public/PPPA-Updated-Guidance-on-Substances-Not-Intended-for-Household-Use.pdf](http://www.cpsc.gov/s3fs-public/PPPA-Updated-Guidance-on-Substances-Not-Intended-for-Household-Use.pdf)

## Part 3: Frequently Asked Questions

### Prescribers/Dispensers of Medications

What is the responsibility of the pharmacist under the PPPA?

- A) The pharmacist **must** dispense oral prescription drugs in special packaging unless there is an exemption, or the patient or prescribing practitioner specifically requests conventional packaging.

Can an individual request that all of their prescriptions be filled in conventional packaging?

- A) Yes. The law does not preclude a pharmacist from relying upon a specific request from a patient to have all of their medications placed in conventional packaging. Many pharmacies choose to have this request in writing (*i.e.*, a blanket waiver). A single request from a patient to dispense a specific prescription in conventional packaging is not a basis for the pharmacist to infer the patient wants all subsequent prescriptions to be dispensed in conventional packaging. Such a request is not a blanket waiver. A patient who previously requested conventional packaging via blanket waiver may later change their mind about the use of such packaging because of changing personal circumstances but may not remember to inform the pharmacist of the change in packaging preference. It is a prudent practice, and recommended by CPSC, for the dispensing pharmacist to check periodically with all patients who have blanket waiver requests on file to ensure that conventional packaging continues to be the preferred packaging choice for the patients' prescription drugs.

If the pharmacist is aware that one of their customers prefers conventional packaging for their prescriptions, can the pharmacist make this decision without the customer's specific request?

- A) No. The pharmacist may advise the customer that he/she has the option of having the prescription dispensed in conventional packaging, but the choice must be the customer or prescriber.

Can a pharmacist dispense a prescription drug in a conventional package in response to a standing order from a physician to dispense it that way?

- A) This can be done only when it applies to refills of a prescription, where the physician has prescribed conventional packaging for that prescription. A drug dispensed to the same person, on a different prescription, of the same or another prescriber, must be dispensed in special packaging, unless the prescription directs the use of conventional packaging, or the purchaser requests it.

Can a physician simply check a box on a prescription blank to indicate to the pharmacist that a drug be dispensed in conventional packaging?

- A) Yes; however, CPSC staff discourages physicians from using prescription blanks and checking a box indicating to the pharmacist that a drug be dispensed in conventional packaging.

Who is responsible for determining at the retail level whether a prescription drug must be packaged in accordance with PPPA standards?

- A) Per [16 CFR § 1701.1\(d\)](#), it is the responsibility of the dispensing pharmacist to ensure that prescription drugs are dispensed in special packaging, unless exempt or otherwise requested.

How does a pharmacist or physician become aware of which drugs are exempt from PPPA standards?

- A) Exemptions to the special packaging requirements can be found under each substance at [16 CFR § 1700.14\(a\)](#). Proposed exemptions are published in the *Federal Register*.

In the case of an antibiotic drug provided by the manufacturer in a granular form to be reconstituted by the pharmacist, who is responsible for providing the special package the pharmacist or the manufacturer?

- A) If the product is in the same container intended to be given to the purchaser, the manufacturer and the pharmacist are both responsible.

Does the same rule apply to drugs dispensed in dropper bottles?

- A) Yes. The special packaging requirements apply to regulated substances no matter the type of package unless otherwise specified in an exemption.

In the case of refills, can prescription bottles and vials be reused?

- A) No. [16 CFR § 1700.14\(a\)\(10\)](#) requires special packaging for prescription drugs meet the provision under [16 CFR § 1700.15\(c\)](#), which prohibits the reuse of special packaging.

Does the regulatory reference to “dosage forms intended for oral administration” include drugs intended for topical application to the teeth or mouth or in a dosage form intended for inhalation?

- A) No. The regulations intend “oral administration” to pertain to drugs that are taken by mouth for a systemic and not local effect. Sublingual preparations are considered “orally administered” even though they are not swallowed. Their effect is systemic and not local to the mouth. Because of the need for quick access to the drug, sublingual nitroglycerin was excluded from the oral prescription drug regulation when it was adopted in 1973.<sup>21</sup>

When a prescription drug is dispensed in a special package, would the pharmacist be in violation of the regulations if a separate conventional closure was included?

- A) Yes. When an applicator is packaged with a product that requires special packaging and the applicator is reasonably expected to replace the original closure of the packaging, the applicator must also be of special packaging design.<sup>22</sup> This is interpreted to mean that any secondary closure that comes packaged with a PPPA-regulated product must also meet special packaging and restricted flow requirements.

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<sup>21</sup> 38 FR 9431 (April 16, 1973).

<sup>22</sup> 63 FR 63602 (November 16, 1998).

Are Investigational New Drugs (INDs) subject to the PPPA standards?

- A) Yes. Oral INDs are subject to the oral prescription drug regulation. Alternatively, if INDs contain any substances already regulated under any of the other PPPA regulations, they would be required to be packaged in special packaging.

Can a pharmacist legally use reversible or other types of dual-purpose packaging for dispensing prescription drugs?

- A) Although these types of closures or packaging are not prohibited, CPSC staff discourages their use because they are likely to result in using the conventional side of the closure which increases the potential for children accessing the contents.

What should I advise a consumer who calls for information when there is a suspected poisoning or child ingestion emergency?

- A) If you are unable to provide the necessary emergency information for the caller or cannot advise them of the proper action to take, CPSC recommends referring the caller to the Poison Control Center or nearest hospital emergency room. The national Poison Control Center phone number is 1-800-222-1222. This number should be on or near your telephone, along with the numbers of the fire and police departments. It also would be prudent to suggest that the caller follow up with their physician.

Can a hospital pharmacist dispense a regulated drug in a conventional package for a patient to use in the hospital without the patient requesting a conventional package?

- A) No, see “Updated Guidance for Institutional Use” section.

Our local hospital sometimes calls upon my pharmacy to provide drugs for patient use within the hospital. Must these drugs be dispensed in special packaging?

- A) Yes, unless a specific exemption under the PPPA applies.

My pharmacy provides drugs to a nursing home. Must these drugs be dispensed in special packaging?

- A) Yes, unless a specific exemption under the PPPA applies.

I know of several physicians who dispense prescription drugs for a fee. Are they subject to the provisions of the PPPA?

- A) Yes. Physicians who dispense drugs (including drug samples) are, and always have been, subject to the regulations under the PPPA. Physicians can, however, dispense drugs in conventional packaging. See “Exceptions and Exemptions” section.

How can a pharmacist or pharmacy determine if the prescription packages they use meet the special packaging standards?

- A) The pharmacy should request the protocol data (test data) from the manufacturer or supplier of the packages. When ordering packaging, pharmacists should be aware that vials and closures from different manufacturers may not function properly when used together. Pharmacists (because they are the entity introducing the regulated substance to the package) are responsible for ensuring that the packages they use comply with the

PPPA and the introduction of the substance does not alter the functionality of the packaging.<sup>23</sup>

## Manufacturers and Packagers

What is the responsibility of manufacturers of prescription drugs subject to the PPPA?

- A) Manufacturers are allowed to send drugs in bulk, conventional packaging that is to be repackaged by the pharmacist. If the manufacturer intends that the package of a particular oral prescription drug is to be dispensed directly to the patient by the pharmacist, the manufacturer must market that drug in special packaging.<sup>24</sup> Such packages are readily recognizable for the most part and often only require relabeling by the pharmacists prior to dispensing. Ultimately, the pharmacist bears the responsibility for ensuring that the special packaging requirements are met.<sup>25</sup>

Can the manufacturer supply to the pharmacist one size of a regulated prescription drug in a conventional package under section 4(a) of the PPPA in the same manner as supplying a noncomplying package for over-the-counter drugs?

- A) There is no provision for a manufacturer or packager to market a single size of a prescription drug in conventional packaging as is the case for over-the-counter medications. Every unit of a prescription drug subject to the PPPA that is packaged by the manufacturer, in a package intended to be dispensed to a consumer, must be in special packaging. Regulated prescription drugs may be dispensed in packaging only at the direction of the prescribing physician or the request of the patient.

Does the drug manufacturer or packager have to test the packaging to determine if it complies with the PPPA standards?

- A) It is ultimately the responsibility of the entity introducing the regulated substance to the package for ensuring that the final product meets the applicable requirements. Package manufacturers will often test their packaging to determine if it meets the effective specifications (e.g., child-resistant and/or senior-friendly). In such cases, the responsible party may rely on the testing conducted by the package manufacturer for certification purposes, but they must ensure that the package will meet the other applicable requirements (general requirements, reuse of special packaging, or restricted flow provisions) when the substance is introduced to the packaging.

Is unit-dose packaging considered to be child resistant?

- A) A blanket statement about whether a specific type of package is child resistant cannot be made. In general, determination of whether a package is considered special packaging is strictly based on whether it meets the various specifications listed at [16 CFR § 1700.15](#) based on test protocols outlined at [16 CFR § 1700.20](#). Unit-dose packaging is evaluated using the same test methods; however, a package failure for unit-dose packaging is when a child opens or gains access to the number of units

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<sup>23</sup> 16 CFR § 1700.15(a).

<sup>24</sup> 16 CFR § 1701.1(b).

<sup>25</sup> 16 CFR § 1701.1(d).



representing a toxic amount or nine units, whichever is less.<sup>26</sup> Because different drugs have different levels of toxicity, a unit-dose package that is compliant for one drug may not be compliant for another, more toxic, drug.

## The Regulatory Agency

What is CPSC's role in informing and educating the public in the use of, and need for, special packaging?

- A) CPSC is part of a coalition called the Poison Prevention Week Council and plays an important role in the NPPW each year by issuing news releases and other audio-visual material encouraging the use of special packaging.

Precisely what does the term "special packaging" mean?

- A) "Special packaging" means packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance within a reasonable time and not difficult for adults without overt disabilities to use properly; however, "special packaging" does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time. Adults without overt disabilities are determined by a screening procedure to determine if they are able to open conventional packaging. To meet PPPA standards, all children need not be prevented from gaining access to the regulated product. This is why the packaging is commonly referred to as child resistant and not child proof. Similarly, all adults need not be able to open the package.

What is the basis for CPSC's determination whether substances are covered by the PPPA?

- A) CPSC must establish a relationship between a particular household substance (because of the way it is packaged) and the potential for serious injury or illness to children as a result of ingesting, handling, or using that substance. Some substances do not lend themselves to this requirement. Ingestion of a product by children does not automatically result in the need for special packaging. For example, many soaps and detergents are frequently ingested but may not cause serious injury or illness to children.

Suppose a pharmacist dispenses a prescription drug in a conventional package. What is CPSC's position?

- A) The law requires that the pharmacist dispense regulated drugs in special packaging. The only exceptions are those instances when the consumer or prescribing physician stipulates that a conventional package be used. Pharmacists, and organizations, who violate the regulations may be prosecuted for civil penalties up to \$120,000 per violation up to a maximum of \$17.15 million for any related series of violations and criminal penalties including imprisonment, fines, and forfeiture of assets.<sup>27</sup> These amounts are effective as of January 1, 2022, and may be adjusted for cost-of-living increases accordingly.

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<sup>26</sup> "Toxic" used here means causing serious injury or illness to a 25 lb. (11.4 kg) child, see 16 CFR § 1700.20(a)(2)(ii).

<sup>27</sup> 86 FR 68244 (December 1, 2021).

What is the basis for selecting the noncomplying package, which the law permits for OTC drugs, regulated under the PPPA?

- A) The manufacturer may select any one of its package sizes as its noncomplying package so long as it also supplies the product in other package sizes which comply with the PPPA standards. The single, noncomplying size must not be the most popular size and must also bear the conspicuous warning “This Package For Households Without Young Children” (or “Package Not Child-Resistant” for small packages). CPSC may require a manufacturer to use only special packaging if the manufacturer has not also supplied the product in popular size packages which comply with the PPPA standards and CPSC finds, after the opportunity for a hearing, that the exclusive use of special packaging is necessary to accomplish the child protection intended by the PPPA.

FDA requires tamper-evident packaging for over-the-counter drugs. Does this replace the requirement for special packaging?

- A) Not necessarily. Evidence of tampering and special packaging are required for different purposes. Although there are some special packages which are also tamper-evident (blisters, unit-of-use), a tamper-evident feature may not meet the requirements for special packaging. FDA requires that evidence of tampering be visually determined on initial contact.<sup>28</sup> The testing procedure for special packaging specifically states that any tamper-resistant feature must be removed prior to testing unless it is a part of the child-resistant design.<sup>29</sup>

What types of special packaging have been approved by the Commission?

- A) CPSC does not approve or certify special packaging. In fact, the PPPA specifically prohibits CPSC from prescribing specific package designs, product content, package quantity, and labeling (with the exception of labeling for noncomplying packages). In addition, the substance could have an effect on compliance (e.g., a volatile solvent could fuse the layers of a push-and-twist closure, or a more toxic drug is used in a blister pack with a higher f-value). The ultimate determination whether a particular package complies with the standards is the responsibility of the manufacturer. CPSC assesses compliance of special packaging based on the review of protocol data and any applicable supporting information (e.g., toxicity determination for unit-dose packaging).

What should a pharmacist or physician do if they know or suspect that PPPA regulations are being violated?

- A) Reports of violative product can be submitted through CPSC’s web portal at: [www.saferproducts.gov](http://www.saferproducts.gov).

Can a state or other political subdivision establish packaging regulations that are more stringent than those promulgated by CPSC?

- A) Mostly no. Section 7(a) of the PPPA prohibits a State or any other political subdivision from establishing packaging requirements for PPPA-regulated substances that are not

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<sup>28</sup> 21 CFR § 211.132.

<sup>29</sup> 16 CFR § 1700.20(a)(1)(ii)(A).

identical to the PPPA.<sup>30</sup> There are some exceptions to this preemption, provided in sections 7(b) and 7(c) of the PPPA. A state may require special packaging of a substance not regulated by CPSC; such requirements are the responsibility of the state and are not enforced by CPSC, nor would CPSC be able to comment or provide assistance on such requirements.

Can a state or other political subdivision establish packaging regulations that are less stringent than those promulgated by CPSC?

A) No.

What are the potential violations for not complying with the PPPA?

A) Drugs that fail to meet the special packaging requirements of the PPPA are “misbranded drugs” pursuant to section 352(p) of the Federal Food, Drug, and Cosmetic Act.<sup>31</sup> It is a prohibited act under the Consumer Product Safety Act to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the US a product that does not meet a rule, regulation, standard, or ban enforced by the CPSC. Violations may subject an individual or their firm to civil or criminal penalties.

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<sup>30</sup> 15 U.S.C. § 1476(a).

<sup>31</sup> 21 U.S.C. § 352(p).