



February 18, 2022

## Poison Prevention Packaging Act (PPPA) Updated Guidance on Substances Not Intended for Household Use

The U.S. Consumer Product Safety Commission's (CPSC or Commission) Office of Compliance and Field Operations is issuing guidance to clarify that CPSC does not recognize an "institutional use" exception for household substances that require special packaging under the Poison Prevention Packaging Act ("PPPA" or "the Act"). Products that meet the definition of a "household substance" must comply with the special packaging requirements under the PPPA, regardless of how the substance is labeled. Even substances intended for institutional use only, and labeled as such, must be in special packaging unless the packaging meets one of the recognized limited exceptions. Although CPSC staff may consider certain factors, discussed below, when determining whether to seek corrective action, no blanket "institutional use" exception exists for covered products. This guidance is effective immediately and supersedes any prior agency guidance concerning institutional use.

### Marketplace Changes Impacting Compliance with the PPPA

In recent years, the distribution, sales, and marketing channels for almost all consumer products, including substances subject to PPPA, have changed dramatically. The distribution channels for many products now involve extensive and multitiered distribution and retail networks, and the manufacturer is often no longer selling directly to individuals or through a brick-and-mortar retailer. Furthermore, the phenomenal growth of online marketplaces makes available to consumers a wider variety of products than ever before.

These changes have led to consumers having greater online access to purchase and consume in their homes household substances in packaging that is not child resistant. Although the manufacturer or re-packager may not sell or otherwise directly introduce into commerce a substance in noncompliant packaging, nor sell it directly to consumers, such noncompliant products, nevertheless, are accessed by consumers. This access is counter to the preventative purpose of the PPPA and places young children it aims to protect at risk.

### Requirements of the PPPA

Enacted in 1970, and found at 15 U.S.C. § 1471, et seq., the PPPA requires certain household substances to be packaged in accordance with special packaging standards found in 16 CFR § 1700.15. Under the Act, a "household substance" is defined as "any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by



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individuals in or about the household” and which is: a hazardous substance<sup>1</sup> (defined in section 1261 U.S.C. § 1(f)); a food, drug, or cosmetic (defined in 21 U.S.C. § 321); or a substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house. A list of substances requiring special packaging can be found in the PPPA’s regulations at 16 CFR § 1700.14. In general, special packaging, often referred to as “child-resistant packaging,” must be 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 while maintaining the effectiveness of such packaging for the duration of normal use. 16 CFR § 1700.15 (child-protocol test for special packaging under the PPPA).

The PPPA contains two statutory exceptions to compliance for household substances that require special packaging. The first is a “one-size exception” applicable to household substances including over-the-counter (“OTC”) drugs intended for elderly or handicapped individuals who might have difficulty opening child-resistant packaging. 15 U.S.C. § 1473(a). Under this exception, the PPPA allows a single noncomplying size of a substance, provided that the substance is also supplied in packages that comply with the PPPA’s special packaging standards. The single size should not be the most popular size and must also bear the conspicuous warning “this package for households without young children.” See 15 U.S.C. §1473(a) and (c); 16 CFR § 1700.5. The “one-size exception” is not applicable to prescription drugs. The second exception applies to prescription drugs dispensed by a pharmacist in packaging that is not child resistant and must be directed by a prescribing doctor or requested by the purchaser. See 15 U.S.C. §1473(b); 16 CFR § 1701.

In addition, the Commission has recognized that bulk packages of prescription drugs intended to be repackaged by the pharmacist before being dispensed to consumers need not use special packaging. However, if the immediate package in which the drugs are distributed by the manufacturer is intended to be the package in which the drugs are dispensed to the consumer, then it must be in special packaging. See 43 Fed. Reg. 11,979 (Mar. 23, 1978); 16 CFR § 1701.

Notably, the PPPA contains no other statutory exceptions to compliance for substances requiring special packaging. Thus, there is no exception for substances used in “institutional” settings (e.g., hospitals, nursing homes, worksites, and other commercial settings).

### Updated Compliance Guidance

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

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<sup>1</sup> CPSC’s regulation at 16 CFR § 1701.3 interprets “household substance,” stating that unless otherwise indicated in 16 CFR § 1700.14(a), the Commission determined that the term “household substance” only applies to hazardous substances packaged in containers with a capacity of less than 5 gallons.



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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 further changes in the marketplace may dictate additional factors for consideration.

To the extent this guidance is inconsistent with any materials previously distributed, this guidance supersedes those materials. Again, the law does not provide for any "institutional use" exception to the PPPA.

## Contact Information

For additional information regarding this updated guidance, please contact [RegulatedCMT@cpsc.gov](mailto:RegulatedCMT@cpsc.gov).