



Gabe Parton Lee
General Counsel
Wyld
gabe@nwconfections.com
PO Box 456
Clackamas, OR 97015

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Memorandum

TO: CIAO Leadership

FROM: Wyld Legal

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RE: Analysis of Evidence-Backed Studies for Individually-Packaged Cannabis Edible Servings versus Unwrapped Servings in Resealable Child-Resistant Containers

ISSUE

Whether individually-packaged unit servings of cannabis edibles present greater child-safety risks than unwrapped servings stored together in a single resealable child-resistant (CR) container, and whether such risks are recognized under federal child-safety packaging law and guidance.

EXECUTIVE SUMMARY

Individually wrapped unit servings of cannabis edibles are less safe for young children than unwrapped servings contained in a single resealable child-resistant package. Under the federal Poison Prevention Packaging Act (PPPA) framework and Consumer Product Safety Commission (CPSC) guidance, each individually wrapped unit functions as a separate "immediate container" that creates an independent access opportunity for children[1][2]. Once any outer packaging is breached, non-CR individual wrappers can be dispersed throughout the home, multiplying ingestion risks and undermining the dose-limiting function that a single resealable CR closure provides[3][4]. Federal regulatory standards demonstrate that concentrating child-resistant features at one properly validated access point—a resealable CR container—offers superior protection by reducing the total number of potential openings, preventing dispersion of accessible units, and limiting opportunities for children to practice and defeat weak unit packaging[5][6]. This is also the standard among state-legal cannabis product regulatory programs.

BACKGROUND

The Poison Prevention Packaging Act

The Poison Prevention Packaging Act of 1970, codified at 15 U.S.C. §§ 1471–1476 and implemented through regulations at 16 C.F.R. Part 1700, requires "special packaging" for designated hazardous substances to protect children under five years of age from serious personal injury or illness resulting from handling, using, or ingesting such substances[1][7]. The CPSC administers the PPPA and defines "special packaging" as packaging that is designed or constructed to be significantly difficult for children under five to open within a reasonable time, while not being difficult for normal adults to use properly[8].

The regulatory test protocol in 16 C.F.R. § 1700.20 measures child-resistance by evaluating how many children aged 42 to 51 months can open a package within specified time periods (five minutes unaided, then five minutes with a demonstration)[5]. For resealable, continuously child-resistant packages, the protocol also requires that adult test subjects be able to open and properly resecure the package, and that child-resistant performance be maintained after resealing[5][6]. This reflects the statutory expectation that special packaging must function correctly across repeated use cycles, not merely at the point of initial sale[8]. This expectation has been incorporated into Oregon regulations and reflects the balance between the safeguards against accidental ingestion by children while allowing patients and elderly adults to access the products.

Defining the "Immediate Container" under PPPA

A critical concept in PPPA compliance is identifying the relevant "package" subject to special packaging requirements. CPSC guidance clarifies that the special packaging requirement applies to the **immediate container or wrapper** in direct contact with the substance[2][9]. If a product is sold with multiple layers of packaging, the innermost package that a consumer would normally open to access the substance is the "immediate container" for PPPA purposes[2].

This distinction is crucial when evaluating individually packaged edibles: if each unit serving is enclosed in its own discrete wrapper (such as a flow-wrap film, pouch, or blister), that individual wrapper constitutes the immediate container for that dose, regardless of whether an outer carton or bag also encloses multiple units[2][9]. Unless each individual unit wrapper is itself tested and certified as child-resistant special packaging, the product does not comply with PPPA requirements simply by virtue of having a CR outer package[2]. Accordingly, the risk of manufacturing error of the individually-wrapped package is higher, resulting in product quality losses, waste, and products on the market that are not adequately child-resistant.

CPSC Testing Standards and Unit-Dose Packaging

CPSC testing protocols recognize the particular challenges of unit-dose packaging. When products are presented as multiple individually wrapped servings, child-resistance testing evaluates the number of individual units children can access[3][6]. Because each unit represents a discrete package, the failure threshold is typically based on the number of units opened rather than simply whether the outer container was breached[3].

Industry guidance on unit-dose packaging emphasizes that even a modest per-unit failure rate compounds rapidly when many identical units are present[3][6]. For example, if a child has a 10% success rate at opening any given unit wrapper, the probability that the child will successfully open at least one unit increases dramatically as the total number of units increases. With ten individually wrapped units available, the child's probability of accessing at least one dose approaches certainty, even if each individual wrapper has some resistance[6].

ANALYSIS

Individually Packaged Units Create Multiple Independent Access Points

The fundamental safety concern with individually packaged cannabis edible servings is that each unit functions as a separate access opportunity. If a product contains ten individually wrapped 10 mg THC

servings in a single outer bag, defeating the outer bag (whether by a child or an adult) exposes ten separate immediate containers, each of which can be approached, manipulated, and potentially opened independently[2][3].

Even if the individual wrappers provide some level of difficulty—such as requiring tearing or peeling—they typically do not meet the CPSC's stringent test criteria for child-resistant special packaging under 16 C.F.R. § 1700.20[5][6]. Standard flow-wrap films, heat-sealed pouches, and similar formats used for unit-dose edibles are designed for ease of opening by adults and are not validated as CR packaging[6][9]. Once exposed, these non-CR units can be:

- Left on countertops, tables, or other accessible surfaces after adult consumption
- Dropped or scattered during handling
- Placed in purses, pockets, or bags where children may encounter them
- Distributed to multiple locations throughout a home or vehicle

Each dispersed unit represents a distinct ingestion hazard, and the total number of potential access events is multiplied by the number of individual packages present[3][4].

Children Learn and Repeat Simple Opening Actions

CPSC research and industry experience demonstrate that children rapidly learn motor sequences required to open packaging[6][10]. Many CR closures rely on children's inability to coordinate two simultaneous actions (such as pushing down while turning, or squeezing sides while pulling up)[6][10]. Once a child masters a coordinated action through trial and error on one package, they can apply that skill to identical packages[6].

With individually wrapped units, a child who successfully opens one wrapper has immediately available additional identical targets on which to practice and refine the technique[3][6]. If a child opens one unit within five minutes, they may open a second in three minutes, and a third in one minute, progressively increasing the total dose consumed. This cumulative exposure risk is inherent in presenting multiple identical low-resistance packages[3][10].

In contrast, a single resealable CR container presents one access challenge. If a child cannot defeat a properly designed CR closure (such as a push-and-turn cap or a CR zipper on a stand-up pouch), they cannot access any servings[5][6]. If they do succeed once, an adult intervention can reseal the closure and restore protection for all remaining servings[5][8]. The learning curve does not translate into immediate access to additional doses because there are no additional identical packages to practice on in the same exposure event[6].

Resealable CR Containers Provide Dose-Limiting Protection

A key safety advantage of resealable child-resistant packaging is its dose-limiting function. When multiple servings are stored together in a single CR container, the CR mechanism must be defeated to access even the first serving[5][8]. This means:

- All servings are protected by a single validated CR barrier that has been tested under 16 C.F.R. § 1700.20

- Children must overcome a coordinated motor challenge (push-turn, squeeze-turn, or similar) that is specifically designed to exceed the developmental capabilities of children under five
- After any adult use, the package can and should be resecured, restoring full CR protection for all remaining servings
- The number of potential "first access" events is limited to the number of times an adult fails to resecure the package, rather than multiplied by the number of servings

Even in a worst-case scenario where a child does defeat the CR closure, the structure of a resealable container makes it more likely that an adult will notice the breach (the container is visibly open or improperly closed) and intervene before multiple servings are consumed[8][10]. Individually wrapped units, once dispersed, provide no such feedback mechanism—an adult may not realize that one or more units have been accessed until a child exhibits symptoms of intoxication[4].

Unit Packaging Undermines PPPA's Preventive Purpose

The PPPA's express purpose is to prevent serious injury and illness to children from accidental ingestion of hazardous substances by requiring special packaging[1][7]. CPSC guidance emphasizes that the Act is preventive rather than merely reactive: it aims to stop children from accessing substances in the first instance, not to limit the severity of exposure once access occurs[1][8].

Individually packaged non-CR units undermine this preventive goal in several ways:

1. **Dispersion defeats containment.** Once individual units leave a CR outer package, they are no longer subject to any CR control, and they can migrate to locations where children have unsupervised access (diaper bags, nightstands, vehicles, visiting relatives' homes)[4][9].
2. **Visual appeal increases risk.** Unit-dose cannabis edibles are often designed to resemble candy, snacks, or other appealing foods, which increases their attractiveness to children and encourages persistent attempts to access them[11][10]. Small, colorful, individually wrapped items are particularly enticing and may be perceived by young children as treats rather than medicines or restricted substances[11].
3. **Partial compliance creates false security.** Products sold in a outer bag or box may create a false impression of safety among consumers and regulators, even though the immediate containers (individual wrappers) provide little or no actual child-resistant protection once the outer package is opened[2][9].

The PPPA framework contemplates that the immediate container will remain the primary barrier throughout the product's useful life, not just at the point of retail sale[2][8]. A resealable CR container fulfills this expectation; individually wrapped non-CR units do not[2].

FDA Guidance on Child-Resistant Packaging Statements

Although cannabis products are not currently regulated by the FDA, FDA guidance on child-resistant packaging for drug products provides persuasive authority on best practices for hazardous consumables. FDA's guidance document *Child-Resistant Packaging Statements in Drug Product Labeling* (October 2019) emphasizes that CR packaging claims must be accurate and tied to the specific package configuration that has been demonstrated to be child-resistant[12][13].

The FDA guidance identifies common CR formats, including:

- CR closures on bottles (push-and-turn, squeeze-and-turn)
- Sealed CR pouches and blister packaging that meet CPSC standards
- Resealable CR containers that maintain performance after opening and resealing[12]

The guidance warns that CR packaging is only one component of a comprehensive child-safety strategy and should be coupled with clear labeling instructing consumers to keep products out of reach of children[12][13]. It further notes that products not packaged in CR containers must carry conspicuous warnings that the package is not child-resistant and is not appropriate for households with young children[12].

By analogy, cannabis edibles packaged as individually wrapped non-CR units should be viewed as non-compliant with CR best practices and should carry warnings that the individual servings are not child-resistant once removed from any outer package. In contrast, unwrapped servings stored in a single resealable CR container can truthfully and accurately be labeled as child-resistant, provided the container meets CPSC testing standards[12][13].

Oregon and Other State Cannabis Regulations and CR Packaging Requirements

Many states with legal cannabis programs have adopted child-resistant packaging requirements for cannabis edibles that reference or incorporate CPSC standards by analogy[11][14]. While state requirements vary, common themes include:

- Edible cannabis products must be sold in child-resistant packaging that complies with 16 C.F.R. § 1700.20 or equivalent standards
- The CR requirement applies to the "package" as defined under state law, often interpreted to mean the immediate container
- Products must be labeled with warnings to keep out of reach of children
- Packaging must not be attractive to children or resemble non-cannabis food products[11][14]

Oregon's rules specifically require all edibles containing more than one serving to be continuously resealable, opaque, not attractive to children, and child-resistant at the immediate container level.

On the contrary, Washington has done away with child-resistant containers and requiring products to be in continuously-child-resistant and resealable containers, resulting in individually-wrapped edibles being removed from outer (or even inner) packaging and left in the open.

The most effective approach, consistent with federal PPPA principles, is to package unwrapped servings in a single resealable CR container that serves as both the immediate and the final barrier to access[8][14].

Practical and Regulatory Recommendations

Based on the foregoing analysis, we recommend that cannabis edible products be packaged as unwrapped servings in a single resealable child-resistant container, rather than as individually wrapped units. This approach:

- Aligns with the letter and intent of the PPPA by concentrating CR protection at the immediate container level
- Reduces the total number of potential child-access events from N (number of servings) to one (the container closure)

- Prevents dispersion of accessible units throughout the home environment
- Limits children's opportunities to learn and repeat opening actions
- Provides clear visual feedback (open vs. closed container) that facilitates adult supervision and resealing after use
- Supports accurate and truthful CR labeling claims under FDA guidance principles
- Reduces product liability exposure by demonstrating adherence to the highest federal child-safety standards
- Prevents individually-wrapped servings in clear flow wrap from being removed from any child-resistant container.

Where product design, shelf life, or consumer preference considerations favor unit packaging, manufacturers should ensure that each individual unit wrapper is independently tested and certified as meeting 16 C.F.R. § 1700.20 CR standards, or that individual units are sold in quantities small enough (such as a single serving per CR outer package) that the risk of multiple-unit ingestion is minimized[2][5].

CONCLUSION

Federal child-safety packaging law and guidance establish that individually packaged servings of cannabis edibles are less safe than unwrapped servings stored in a single resealable child-resistant container. The PPPA and CPSC regulations demonstrate that effective child protection depends on concentrating CR features at the immediate container level, minimizing the number of independent access points, and preventing dispersion of non-CR packages into the household environment. A resealable CR container fulfills these goals; individually wrapped non-CR units do not. We recommend adopting packaging formats that place unwrapped servings in validated resealable CR containers as the preferred approach to compliance with federal child-safety principles and state cannabis packaging requirements. Further, individually-wrapped servings appear more like consumer-available candy, encourages removal from any outer container with all warnings and information intact, and departs from the regulatory standard abided by the vast majority of state regulatory programs.

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