CHPA

founded 1881

August 3, 2010

Office of the Secretary
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Submitted electronically via www.regulations.gov

Re: **Docket No. CPSC-2010-0038:** *Testing and Labeling Pertaining to Product Certification*

To the Commission:

The Consumer Healthcare Products Association ("CHPA") appreciates the opportunity to provide comments on the Consumer Product Safety Commission's ("CPSC" or "Commission") proposed rule, "Testing and Labeling Pertaining to Product Certification," published in the Federal Register on May 20, 2010. Founded in 1881, CHPA is a national trade association representing leading manufacturers of over-the-counter ("OTC"), non-prescription medicines and dietary supplements.

PPPA Regulated OTC Medicines and Dietary Supplements are Not Children's Products

Many CHPA members manufacturer products with packaging regulated under the Poison Prevention Packaging Act ("PPPA"). The food and drug products manufactured and distributed by our member companies are specifically exempted from the definition of "consumer products." Consumer Product Safety Act, P.L. 92-573, Sections 3(a)(5)(H) and (I)). Therefore, the only food and drug products that fall within the scope of the Commission's regulatory authorities are those for which the Commission has imposed packaging requirements pursuant to the PPPA. P.L. 91-601. These products are specifically enumerated in 16 CFR §1700.14. Further, the Commission's regulatory authority over such products is limited to the packaging.

While some of these OTC medicines and dietary supplements may be labeled for use in children, they are not considered children's products under CPSC laws and regulations. As stated in CPSC's April 10, 2010 proposed rule on the "Interpretation of 'Children's Product'" "products that incorporate performance requirements for child resistance are not children's products as they

Consumer Healthcare Products Association
900 19th Street, NW, Suite 700
Washington, DC 20006
T 202.429.9260 F 202.223.6835
www.chpa-info.org

are designed specifically to ensure that children cannot access the contents." Interpretation of "Children's Products," 75 Fed. Reg. 20,533, 20,534 (April 10, 2010). While the drug or supplement product may be labeled for use in children, the packaging of the products regulated by the Commission is specifically designed to prevent access to the drug or supplement by children.

Proposed Subpart C- "Certification of Children's Products"- is Only Applicable to Children's Products

As you are aware, the CPSA establishes different testing requirements for "children's products" and "nonchildren's products." As currently written, some of the provisions in Subpart C, "Certification of Children's Products," are not explicitly limited to children's products. This is inconsistent with the intent of the provision and requires clarification. For example, the provision on periodic testing (proposed §1107.21), references Subpart B of the proposed rule which relates to testing programs for nonchildren's products. We recognize that Subpart B states that children's product manufacturers can voluntarily establish a reasonable testing program consistent with the requirements for nonchildren's product manufacturers but the reference in Subpart C could lead to confusion. To clarify, §1107.21 should be revised as follows:

> (a) Each manufacturer [of a children's product] must conduct periodic testing…(b) If a manufacturer [of a children's product] has implemented a reasonable testing program…(c) If a manufacturer [of a children's product] has not implemented a reasonable testing program…(d) For a [children's product] produced or imported at low volumes….

Additional revisions should be made to the other provisions in Subpart C that do not explicitly qualify the term "manufacturer" with "of a children's product." As intended by the title to the subpart, "Certification of Children's Products," the entirety of this subsection is only applicable to manufacturers of children's products.

Existing PPPA Testing Standards Meet Requirements for a Reasonable Testing Program

We support the Commission's efforts to establish requirements for a reasonable testing program for nonchildren's products. As you are aware, 16 C.F.R. 1700.20 outlines the rigorous testing protocol for products required to be packaged in child resistant packaging pursuant to the PPPA. We strongly believe that these requirements meet the definition of a "reasonable testing program." Since implementation of the PPPA in the early 1970's, these requirements have dramatically reduced the number of deaths caused by unintentional ingestion of medicines by children. CPSC, Poison Prevention Packaging: A Guide for Healthcare Professionals (2005),

available at http://www.cpsc.gov/cpscpub/pubs/384.pdf. As noted in the Commission's online Frequently Asked Questions document:

> The child resistance and senior friendly testing data (also known as protocol data) obtained in accordance with the procedures described under 16 C.F.R. 1700.20 may be used by the importer or domestic packager to support its certification. **The packager can rely upon this data as the basis for the reasonable testing program**. There is **no expiration date on these tests and no requirement to retest** so long as the tests adequately reflect the current packaging used.

CPSC, Consumer Product Safety Improvement Act Frequently Asked Questions (posted 12/10/08), available at http://www.cpsc.gov/about/cpsia/faq/faqs.html (emphasis added).

The history of success of the PPPA procedures and CPSC's stated position on PPPA testing provides manufacturers complying with the PPPA laws and regulations a "high degree of assurance" that their products comply with the relevant applicable rules. *See* proposed § 1107.10(a). Similar to the existing testing programs listed in Table 1 of the Description of the Proposed Rule, the PPPA and its accompanying regulations establish a mandatory testing program that should not be superseded by proposed §1107.10. Therefore, PPPA products should not be required to adhere to the provisions of proposed §1107.10, as a "reasonable testing program" already exists for these products.

***

If the Commission disagrees with CHPA's position that PPPA products should be exempt from the proposed rule due to the existing mandatory PPPA testing program, we recommend the following changes to the proposed regulatory language of § 1107.10 (in addition to the revision to Subpart C- §1107.21 discussed above).

1. **Retesting is Not Required for PPPA Products Unless There is a Change That Could Affect Compliance with PPPA Regulations**

As stated by CPSC and noted above, PPPA packaged products do not require retesting unless there is a change that could affect compliance with PPPA regulations. Therefore, the language of proposed §1107.10(b)(3)(iii) should be revised to state:

> The production testing must ensure that, if the samples selected for production testing comply with an applicable rule, ban, standard, or regulation, there is a high degree of assurance that the untested

> products manufactured also will comply with the applicable rule, ban, standard, or regulation.

All references to testing intervals have been removed as in some instances, such as with PPPA products, time based interval retesting of a product is not necessary under a "reasonable testing program." Stating that the "testing interval selected must be short enough" incorrectly implies that testing requirements should be based on time as opposed to being time-independent and pursuant to a change that could affect compliance to the applicable rule.

2. **Product Specification Documentation Should Not Require Listing of Applicable Rules, Bans, Standards, or Regulations**

Requiring product specifications to list "the applicable rules, bans, standards, or regulations to which the product is subject" is unnecessary as it is duplicative of information already included on the general conformity certificate for a product. This requirement would place a tremendous resource burden on manufacturers without any added value under a reasonable testing program for CPSC regulated products. Therefore, the introduction to §1107.10(b)(1) should be revised to state as follows:

> *Product Specification:* The product specification is a description of the consumer product. A product specification should describe the product listed on a general conformity certification in sufficient detail…

3. **Definition of "Identical in All Material Respects" Should be Revised for Clarification Purposes**

The definition of "identical in all material respects" should be modified to clarify the intent of the rule. Specifically, the term as defined in § 1107.2 should be revised to state as follows:

> *Identical in all material respects* means there is no difference between the sample and the finished product that could affect compliance to the applicable rules.

4. **The Terms "Production Testing Plan" and "Remedial Action Plan" Should be Expanded to Include "Procedures"**

Proposed §1107.10 should be revised to expand the terms "Production Testing Plan" and "Remedial Action Plan" to include procedures. As drafted, the term "plan" may be interpreted too narrowly to allow for the range of methods manufacturers may utilize to meet the underlying substantive requirements outlined in the proposed rule.

Specifically, the term "production testing plan" should be replaced with "production testing plan or procedures" throughout proposed §1107.10(b)(3) and anywhere else the term is used in the proposed rule. Further, the term "remedial action plan" should be replaced with "remedial action plan or procedures" throughout proposed §1107.10(b)(4) and anywhere else the term is used in the proposed rule.

5. **Multiple Manufacturing Sites Can Have the Same Product Specifications and Production Testing Plan or Procedures**

The provisions of §1107.10 should allow multiple manufacturing sites to share common product specifications and production testing plan or procedures. Specifically, § 1107.10(b)(1)(iii) should be revised to state:

> Each consumer product must be covered by a product specification.

Further, §1107.10(b)(3)(ii) should be revised to state:

> Each manufacturing site shall be covered by a production testing plan or procedures.

Manufacturers of PPPA regulated products may utilize the same product specification and/or production testing plan or procedures across multiple manufacturing sites. This is appropriate under the requirements for a reasonable testing program due to the nature of PPPA regulated products and limited requirements for retesting once the design of a product has been shown to meet the child resistance standards.

CHPA members thank the CPSC for the opportunity to provide our comments on this important issue. If the Commission has any questions or if CHPA can be of any assistance, please let us know.

Sincerely,

Alison Manhoff

Alison Manhoff
Deputy General Counsel
Consumer Healthcare Products Association