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October 29, 2008

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East West Highway
Bethesda, Maryland, 20814

Via E-Mail and Facsimile

Re: Section 102 Certificate Requirements

To the Commission:

On behalf of the member companies of the Consumer Healthcare Products Association (CHPA), I am responding to the Commission's request for comments on the Consumer Product Safety Improvement Act of 2008 (CPSIA). CHPA is the trade association representing leading manufacturers of over-the-counter, nonprescription medicines and dietary supplements.

Our member companies, like those in many other industry sectors, are just beginning to assess the impact of the new general conformity certification requirement imposed by the CPSIA. CHPA has joined a number of other trade associations in submitting joint letters requesting that the Commission exercise enforcement discretion with respect to the new certification requirement, and that the Commission meet with representatives of our associations and member companies for further discussion. It is simply not feasible for all manufacturers, distributors, and retailers to fully understand and comply with this requirement by the effective date of November 12, 2008.

We appreciate that the Commission has issued some compliance guidance regarding certifications, but significant questions remain. Please consider the points covered in this letter only as initial comments, as we believe additional concerns and questions will arise as our member companies continue to grapple with the logistics challenges of complying with the certification requirement.

Scope of Section 102(a)(1)

The CPSIA (P.L. 110-314) was signed into law on August 14, 2008. Section 102(a)(1) of the Act imposes a general conformity certification requirement that takes effect ninety days following enactment (November 12th). Compliance with this requirement entails preparing and distributing a certificate attesting to a product's conformity with all Commission "rules, bans, standards, or regulations applicable to the product."

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Section 102(a)(1) extends the certification requirement to “a product which is subject to a consumer product safety rule under this Act or similar rule, ban, standard, or regulation under any other Act enforced by the Commission.” 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). We believe 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 Poison Prevention Packaging Act (P.L. 91-601). These products are specifically enumerated in 16 CFR §1700.14.

We do not share the Commission’s view that a product subject to a “consumer product safety rule...or similar rule” includes products that are not “consumer products” as explicitly defined by the Consumer Product Safety Act. We urge the Commission to reconsider whether this is in fact the meaning and intent of this section of the CPSIA.

Reasonable Testing Program

Testing for products’ compliance with Poison Prevention Packaging Act (PPPA) standards typically is done once for each package design, to confirm that manufacturing specifications are appropriate. Compliance with good manufacturing practices assures continuous adherence to those specifications once they are established, and there is no need for follow up testing unless manufacturing specifications are changed in a manner that could affect PPPA compliance. We urge the Commission to recognize that these practices constitute a “reasonable testing program”, as referenced in Section 102(a)(1)(A).

Distribution and Availability of Certifications

Section 102 requires that general conformity certificates “shall accompany the applicable product or shipment of products covered by the same certificate and a copy of the certificate shall be furnished to each distributor or retailer of the product.”

The realities of manufacturing and distribution logistics make compliance with these requirements extremely complex, especially when the specific required information enumerated in the statute is taken into account. It is essential, therefore, that the Commission exercise the greatest possible flexibility in interpreting what is meant by a “certificate” and in recognizing the wide variety of means by which certification information may be distributed.

As Commission staff have suggested, it will be necessary for many manufacturers to utilize electronic means to comply with the CPSIA’s requirement to provide certifications that both “accompany” products or

shipments and are “furnished to each distributor or retailer.” For this reason, we urge the Commission to recognize not only that a “certificate” as described in Section 102 need not be a physical piece of paper, but also that providing the required information through one or more physical and electronic means in combination would constitute a “virtual certificate” meeting the underlying goals of this section.

For many manufacturers, a single shipment could include as many as several hundred products. Unfortunately, the requirement to identify “date and place of manufacture” means that the products in a shipment must be further disaggregated for certification purposes into manufacturing lots. So while the statute appears to envision a neat scenario of “one shipment, one certificate”, in fact a shipment could require hundreds of certificates. Even if physical certificates are not required, certification information for a given shipment still would have to reflect the specificity necessary to associate “date and place of manufacture” information with each lot contained within a shipment.

A large shipment is likely to be broken down into smaller units and products commingled in distribution before they reach individual retail stores. This means that even if an overall certification is prepared for a specific shipment, the logistical demands of “furnishing” certification information to end retailer recipients by physically associating certification information with sub-shipment packaging, lot by lot, would be overwhelming.

A web-based product code lookup system might enable both distributors and retailers to confirm the existence and details of certifications applicable to specific products, regardless of the original shipment in which those products were contained. A manufacturer-specific World Wide Web uniform resource locator (URL) could be provided with shipments, and to distributors and retailers. Providing “date and place of manufacture” information through a web system could be problematic, however, and this information might need to be provided separately on packaging.

Our member companies are in the early stages of sorting out these challenges, and we cannot represent at this time that a web-based system answers every problem. Undoubtedly, there are additional questions and obstacles that we have not yet identified. It is a certainty, however, that it will be necessary to allow elements of the certification information to be provided separately, physically and/or electronically, and, depending on the specific element, potentially associated with products at specific packaging levels, from shipment to small-lot packaging.

Identity of Manufacturers and Multiple Certifications

We would appreciate further clarity regarding which entities need to certify and/or be listed as indicated by the Sample General Certification of Conformity and the accompanying instructions prepared by Commission staff. The definitions of “manufacturer” and “private labeler” in the Consumer Product Safety Act (Sections

3(a)(11) and (12)) only apply to “consumer products”, not to food or drugs, since those products are excluded from consumer products by the Act’s definition. If food and drug products are subject to Section 102’s general conformity certification requirement, it is pursuant to packaging requirements under the PPPA, rather than under the CSPA with its manufacturing definition that is specific to consumer products. Does this mean that the manufacturer that packages the food or drug product, rather than the manufacturer of the packaged product, is the entity expected to provide the certification?

We seek additional explanation regarding the type of questions that can arise in the following scenario: Company A is marketing a drug product and uses contract company B for manufacturing, contract company C for primary packaging, labeling and testing, and contract company D for secondary packaging. Is Company A the manufacturer certifying in Item 3, or a private labeler certifying in Item 5? Is Company B, C, or D the entity to list in Item 7 for place of manufacture? If Company A is considered a private labeler, is company B to provide a certification as well for the same product?

Clearly, this scenario could give rise to multiple parties issuing certifications for the same underlying product, which would be both confusing and inefficient. We urge the Commission to issue further guidance ensuring that only one certification need to be prepared for a given product, and that the certifying responsibility clearly rests with a single, easily identifiable entity no matter the complexities of the multi-party production process.

We also seek clarification on whether a product imported for further packaging before it enters the retail distribution chain must be accompanied by a certification, or if the certification requirement does not arise until the retail-ready product is distributed in an initial shipment. We believe the latter is the sensible interpretation.

Pediatric Drug Products

We understand that commission may be considering the applicability of the CPSIA’s third-party testing requirements to pediatric drug products. The third party testing requirement found in Section 102(a)(2), however, clearly applies only to “children’s products”, which are specifically defined as a subset of “consumer products.” Consumer Product Safety Act, P.L. 92-573, Sections 3(a)(2). As referenced above, foods and drugs are specifically exempted from the definition of “consumer products”, and therefore the CPSIA’s third party testing requirements do not apply to pediatric drug products.

On behalf of our member companies, thank you for considering these initial comments on the general conformity certification requirement of the Consumer Product Safety Improvement Act. This requirement

will be onerous in the best of circumstances, and has the potential to be enormously burdensome if the Commission does not accord manufacturers maximum compliance flexibility.

We greatly appreciate you taking the issues raised in this letter under advisement, and trust you will address them in future guidance as soon as practicable. We and our member companies will continue communicating with the Commission as we sort through these challenges.

Yours truly,

A handwritten signature in black ink, appearing to read "Andrew C. Fish". The signature is written in a cursive, flowing style.

Andrew C. Fish
Senior Vice President, Legal & Government Affairs,
and General Counsel

cc: Ms. Patsy Semple, Executive Director