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July 20, 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-2010-0041: *Publically Available Consumer Product Safety Information Database***

Dear Mr. Stevenson:

The Consumer Healthcare Products Association (“CHPA”) appreciates the opportunity to provide comments on the Consumer Product Safety Commission’s (“CPSC” or “Commission”) proposed rule, “Publically Available Consumer Product Safety Information Database,” published in the Federal Register on May 24, 2010. Founded in 1881, CHPA is a national trade association representing leading manufacturers of over-the-counter (“OTC”), non-prescription medicines and dietary supplements. As described in more detail below, in order to ensure the continued safe reporting of adverse events associated with our members’ products and prevent consumer confusion, we strongly believe OTC and dietary supplement product incident reports should not be included in the CPSC safety incident database.

Food and Drugs are Not Regulated as “Consumer Products”

Pursuant to Section 212 of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”), the Commission is required to implement a “database on the safety of consumer products, and other products or substances regulated by the Commission.” As you are aware, the food and drug products manufactured and distributed by our member companies are specifically exempted from the CPSC definition of “consumer products” and these products are highly regulated by the Food and Drug Administration (“FDA”). 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 (“PPPA”) (P.L. 91-601). Further, the Commission’s regulatory authority over such products is limited to the product packaging.

**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

FDA has an Established Safety Reporting System for OTCs and Dietary Supplements

While the implementing language for CPSC's database references products regulated by the Commission that may not be "consumer products," we do not believe the intent of this provision of the law was to include OTCs and dietary supplements. As you are likely aware, FDA has an expansive and well-established adverse event reporting system for OTCs and dietary supplements, MedWatch (<http://www.fda.gov/Safety/MedWatch/default.htm>). Under the Federal Food Drug and Cosmetic Act, as amended in 2006 by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (P.L. 109-462), manufacturers of OTCs and dietary supplements are required to report "serious adverse events" to FDA. Further, OTC drug and dietary supplement product labeling is required to include manufacturer contact information to enable consumers to report such events to manufacturers. P.L. 109-462, 2(d). Additionally, the MedWatch system also includes voluntary adverse event reporting procedures for consumers (see <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm>). The timely reporting of adverse events to FDA through this robust system is a critical mechanism for ensuring the health and safety of the American public.

CPSC's Database would Create Consumer Confusion and Delay Critical Reporting to FDA

If the CPSC were to incorporate PPPA regulated drug and dietary supplement product packaging into its safety incident database, it is likely to cause significant consumer confusion. Consumers using drug and dietary supplement products may not distinguish between packaging related consumer safety incidents and incidents related to the underlying drug or dietary supplement (it is also unclear how the consumer will differentiate PPPA regulated packaging from non-PPPA regulated packaging for reporting purposes). Therefore, it is likely that consumers would inadvertently submit important drug or supplement safety information to the CPSC instead of to the manufacturer or FDA, thereby delaying the appropriate review of this important information. Any delay in reporting this information to the manufacturer or FDA could have significant health and safety consequences for consumers.

The background information to the proposed rule states that "reports of harm that fall outside the scope of CPSC regulatory authority will be referred to an appropriate agency or entity with notification of such action to the submitter." As discussed above, the timing of such reporting to FDA is critical to the safety of American consumers. With more than 15,000 consumer reports anticipated annually (and, in addition, 7,500 manufacturer comments and 2,500 or more requests to treat information confidentially or as materially inaccurate), it is not clear that CPSC will have the resources to ensure that critical drug or supplement safety reports are transferred to FDA in a timely manner.

Value of PPPA Regulated Packaging Safety Incident Reports to CPSC is Unclear

Furthermore, we question the value of reporting PPPA regulated packaging safety incidents to CPSC. Unlike many of the "consumer products" regulated by the CPSC, it is improbable that PPPA product packaging will contribute to the types of "harm" (as defined in Section 212 of the CPSIA) common with "consumer products." While "harm" may result from PPPA regulated packaging in cases where children are able to break into the packaging and access the OTC or dietary supplement product, as you

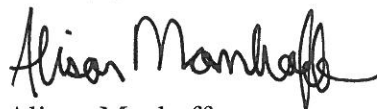
know, PPPA packaging is designed and tested to be child-resistant and not child-proof. Reports of PPPA packaging “failures” are therefore not necessarily a “harm” under the law. Further, packaging related incident reports of this nature will not assist CPSC in achieving its consumer safety goals as child resistant packaging is carefully regulated through the testing protocols required by CPSC regulations. Considering this information, it is unclear what types of PPPA related safety reports CPSC intends to include in the database.

PPPA Regulated Packaging Should Not Be Included in CPSC’s Database

We urge the Commission to carefully consider these concerns when interpreting the meaning and intent of the database provisions of the CPSIA and considering whether the provisions are really intended to include incident reports related to PPPA regulated packaging of OTCs and dietary supplements.¹ If the Commission determines it must incorporate OTC and dietary supplement products with PPPA regulated packaging into the database, it is imperative that the Commission provide sufficient instructions making it clear to the consumer that reports regarding the drug or dietary supplement itself should not be submitted to CPSC and must be reported directly to FDA and/or the manufacturer, as appropriate. The CPSC consumer reporting form must emphasize that only incident reports related to PPPA regulated packaging should be reported. Further, CPSC will need to vigilantly monitor any reports received prior to public posting to ensure the incident report falls within the jurisdiction of the CPSC database and that any reports that should be submitted to FDA are transferred in a timely manner.

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
Associate General Counsel
Consumer Healthcare Products Association

¹ Additionally, while outside the scope of these comments, many of our member companies also manufacturer products in other product classes such as cosmetics and medical devices that may require child resistant packaging under the PPPA or otherwise be regulated by the CPSC. As these products are also highly regulated by FDA, many of the same principles outlined in this letter support their exclusion from the database and we encourage the Commission to carefully consider this information when developing the database.