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Over-the-Counter and Prescription Drug Manufacturers are Granted a One Year Reprieve from the Burdensome Requirements of the Consumer Product Safety Improvement Act

On August 12, 2008, Congress passed the Consumer Product Safety Improvement Act ("CPSIA"), which amended the Consumer Product Safety Act ("CPSA"). One of the more noteworthy requirements imposed by these amendments is a certification standard that would directly impact manufacturers subject to the revised Act, including manufacturers of prescription and over-the-counter drugs. Confronted with the overwhelming task of enforcing these new certification standards the Consumer Product Safety Commission (the "Commission") published a Notice of Stay of Enforcement of Testing and Certification Requirements in the February 9, 2009 Federal Register. 74 Fed. Reg. 6396 (2009). The partial stay effectively delays enforcement of the revised Act until February 10, 2010.

Although prescription and over-the-counter drugs are typically outside the jurisdiction of the Commission, it is responsible for enforcing the "special packaging" standards imposed by the Poison Prevention Act, which includes child-resistant ("CR") packaging of prescription and over-the-counter drugs. As such, drug manufacturers that utilize CR packaging should be aware of and start considering programs to comply with the CPSIA. Prior to the CPSIA amendments, the CPSA required the manufacturers of just eleven types of products to certify that their goods complied with the safety standards imposed under the Act. 15 U.S.C. § 2051-89 (2008). Items subject to the earlier requirement included matchbooks, bicycle helmets, lawn mowers and cigarette lighters amongst other things. Although seemingly unrelated, these diverse items were all subject to specific safety standards, as a result of the potential dangers they posed to consumers. Today, the revised Act's Certificate of Compliance requirement encompasses thousands of goods, including those prescription and over-the-counter drugs that require child resistant packaging.

Fueled by the magnitude of recalled children's products, the CPSIA establishes many new requirements for children's goods and toys, including new lead and chemical restrictions. Although the amendments focus on children's goods, Congress also created new requirements for hundreds of other "manufacturers," who do not manufacture children's products. Under the 2008 amendments, a certification is required for any product "manufactured on or after November 12, 2008" that is subject to a standard under the CPSA or a "similar, rule, ban, standard, or regulation under any other Act enforced by the Commission." 15 U.S.C. § 2063. Similar standards, bans and rules incorporate, but are not limited

to the bans, requirements and labeling rules of the Federal Hazardous Substance Act; the standards of the Flammable Fabrics Act; the "special packaging" standards imposed by the Poison Prevention Act which includes child-resistant packaging of prescription and over-the-counter drugs; and the standards found in the CPSIA, which have not yet become effective. See 16 C.F.R. § 1110. Consequently, the number and types of products now subject to the certification requirement is immense.

Remarkably, the parties that must certify compliance under the amended CPSA are also numerous. According to language of the amendments, every domestic or foreign manufacturer, importer and private labeler must separately certify compliance. 15 U.S.C. § 2063. Fortunately, the Commission quickly realized that coordinating and tracking the certificates from all these entities would be extremely difficult. As a result, the Commission limited the parties subject to the requirement in an effort "to implement the certificate program in a fair and orderly way in its initial phase." 16 C.F.R. § 1110. Under the Certificates of Compliance Rule, only the U.S. importer and in the case of domestically produced products, the US manufacturer need certify compliance at this time. *Id.* § 1110.7 (a)-(b).

The conformity certificate itself must be "based on a test of each product or a reasonable testing program" and must include a variety of information ranging from the contact information for the manufacturer and the individual maintaining the test results, to the date and location where the product was tested. See 15 U.S.C. § 2063; see also 16 C.F.R. § 1110.11. Beyond the mandated content requirements, the certificates must "accompany" each product or shipment of products and be "furnished" to each distributor or retailer of the product. 15 U.S.C. § 2063. Although the certificate does not need to be filed with the Commission or the government, it still "must be furnished to [the Commission] upon request." 16 C.F.R. § 1110.

The "accompany" and "furnish" requirements caused many manufacturers to fear that the Certificate of Compliance must be manifest as a paper document. To the relief of many, including importers and manufacturers who would have struggled to provide paper certificates to a large base of independent retailers, the Commission confirmed that electronic certificates were appropriate as long as they complied with 16 C.F.R. § 1110 and Section 14 of the CPSA. *Id.* § 1110.5. According to the Commission, an electronic certificate satisfies the "accompany" requirement if it is: (1) created before shipment and the date of creation and modification can be verified electronically; (2) identified by a unique identifier; and (3) accessible to the Commission or Customs via a web URL as soon as the product is available for shipment. *Id.* § 1110.13(a)(1)(b). A party fulfills the obligation to "furnish" the certificate to distributors and retailers if the distributors and retailers are "provided a reasonable means to access the certificate." *Id.* § 1110.13(a)(2).

Although the stringent new requirements became effective on November 12, 2008, the certification requirement only affects goods manufactured on or after that date. Moreover, on February 2, 2009, the Commission stayed the applicability of the new certification requirements for certain products, which are not children's goods and did not previously require a general conformity certificate. The stay will remain in effect until February 10, 2010, at which time the Commission will vote to terminate the stay. The Commission noted in the Federal Register the breadth of the new requirements, the impact on small businesses, and its inability to adopt rules covering all aspects of the CPSIA amendments. As such, the Commission is focusing its efforts on rulemaking and enforcement as it pertains to children's products. In so doing, it will attempt to address the confusion surrounding the CPSIA in addition to performing its regular role analyzing products' compliance with substantive safety rules. After the Commission has had the opportunity to provide the necessary guidance on the CPSIA and the stay has passed, it is likely that the Commission will keep its prior promise of strict enforcement. As the Commission previously stated, once the certification requirement is enforced "failure [of importers] to abide by the general certificate requirement will subject shipment to refusal of admission and potential destruction." *Id.* § 1110.

The required conformity certificate will be a significant obligation and burden for foreign importers and domestic manufacturers of prescription drugs and over the counter products with CR packaging. Many companies with products subject to the revised Act unknowingly violated the new requirements from mid-November to February because they did not realize that amendments spurred on by dangerous children's toys affected their products, which are not designed or marketed for children. These companies could have incurred significant fines and the potential destruction of their goods if it were not for the Commission's stay of enforcement. Moreover, these companies will most certainly face significant penalties if they do not consider and implement programs designed to effectuate compliance with the new certification standard scheduled to be implemented next February. The stay should, however, notify Congress that its overly broad language has, perhaps unintentionally, captured thousands of products whose safety will not be improved by the burdensome regulations. It is not clear whether Congress will act to remedy what one can only conclude is an unintended result.

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