



Subject: CPSIA and Lead, Phthalates

Dear Madam/Sir:

Chattem, Inc. has examined the lead content and phthalate limits established by the Consumer Product Safety Improvement Act of 2008 ("CPSIA") to determine whether the provisions apply to Chattem's products.

As you may know, the Consumer Product Safety Commission ("CPSC"), as a general matter, has taken the position that product containers and packaging are subject to its jurisdiction under the Poison Prevention Packaging Act ("PPPA").

The new lead limits under §101 of the CPSIA applies to children's products. A "children's product" is defined as "a consumer product designed or intended primarily for a child 12 years of age or younger." See 15 USC 2052(a)(2). This definition specifically incorporates the definition of "consumer product" under the Consumer Product Safety Improvement Act which excludes "drugs, devices, or cosmetics" as defined under the Federal Food, Drug, and Cosmetic Act. Based on the Commission guidance, pharmaceutical container are not children's products, the new lead content limit does not apply to its products or packaging. Accordingly, Chattem is not required to test or certify to the "lead limit" provision.

As for phthalates, the CPSIA prohibition applies to a "children's toy or child care article." See CPSIA §108(a). The term "children's toy" is defined as "a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays." CPSIA §108(e)(1)(B). The term "child care article" is defined as "a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething." CPSIA §108(e)(1)(C).

Chattem's products do not meet the definitions of "children's toy" or "child care article," therefore, the phthalate ban does not apply. Chattem is not required to test or certify this provision either.

Sincerely,

A handwritten signature in black ink that reads "David Grob". The signature is written in a cursive, slightly slanted style.

David Grob
Director, Regulatory Affairs and Product Safety