



Subject: CPSIA – Applicability of General Conformity Certification

RE: Products Not Subject to the PPPA's Child-Resistant Packaging Requirements - Kaopectate Antidiarrheal OTC drug products

Dear Sir or Madam,

As you may be aware, the Consumer Product Safety Improvement Act of 2008 (CPSIA) was signed into law on August 14, 2008 and it imposes compliance certification requirements on a wide variety of consumer products. Under the law, for applicable products manufactured on or after November 12, 2008, manufacturers and private labelers are required to provide certification that the product complies with relevant rules, bans, standards and regulations enforced by the Consumer Product Safety Commission (CPSC).

Based on the Commission's current interpretation of CPSIA, as reflected in the CPSC final rule issued on November 18, 2008, only importers and domestic manufacturers are required to issue the "General Conformity Certification" as to comply with CPSC rules, bans, standards and regulations. As in the past, companies can continue to voluntarily choose to follow certain CPSC rules, bans, standards or regulations if not required to do so, but those voluntarily adhered to do not require General Conformity Certification.

The General Certification requirement applies to Over-the-Counter (OTC) medicines and dietary supplements subject to the Child-Resistant Packaging (CRP) requirements of the Poison Prevention Packaging Act (PPPA) and its implementing regulations. Additional certification requirements may apply as to packaging and other products not applicable to this notification.

Chattem assures that all of our products comply with the applicable CPSC regulations including those regarding Child-Resistant Packaging. In fact, our Kaopectate antidiarrheal OTC drug products bear CRP container-closure systems although not required under 16 CFR §1700.14 (the PPPA). Because Chattem's Kaopectate products are not required to use CRP, Chattem is not required to submit a General Conformity Certification under CPSIA.

If you should have any questions, please feel free to contact me directly at 423-822-3367 or I can be reached via email at david.schilling@chattem.com.

Sincerely,

A handwritten signature in blue ink that reads "David M. Schilling".

David Schilling
Associate Director, Regulatory Affairs
Chattem, Inc.

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