LOG OF MEETING

SUBJECT: Petition (PP03-1) to Amend Child-Resistance Testing Pass/Fail Criterion for Unit Packaging

DATE OF MEETING: December 7, 2004

PLACE: Keller & Heckman, 1001 G Street, NW Washington, DC

LOG ENTRY SOURCE: Suzanne Barone, Ph.D., Pharmacologist, HS

COMMISSION REPRESENTATIVE: Suzanne Barone, Ph.D.

NON-COMMISSION REPRESENTATIVES: See attached sheet.

SUMMARY OF MEETING:

Suzanne Barone, Ph.D., project manager for petition PP03-1, was invited to the Healthcare Compliance Packaging Council's (HCPC) full membership meeting to discuss the CPSC staff's recommendation to deny the petition to amend the child-resistance testing pass/fail criterion for unit packaging. The petition had been submitted to the Commission by the HCPC. Copies of the Executive Summary of the briefing package were given to the meeting attendees by Dr. Barone (copy attached to this summary). A copy of the briefing memorandum was provided to each attendee in meeting packets provided by the HCPC at the meeting.

Dr. Barone discussed that the CPSC staff agreed with the original discussions made by the FDA in the early 1970s that protection of a child from serious injury or illness (toxicity of the drug) was the most important criterion in determining child-resistance of unit packaging. Dr. Barone described that many of the commenters listed drugs and chemicals that would cause serious injury or illness to a young child if less than 8 units were ingested. Dr. Barone also stated that the issue of calculating the amount of substance that could cause serious injury was important and the CPSC staff agreed that this issue merited further study especially in light of the study submitted by ANEC, the European consumer group. She also stated that any company not wanting to calculate toxicity could use F=1 packaging which is available on the market. There was also a discussion of the European standards related to this issue.

Dr. Barone ended the meeting by stating that the Commission had not decided on this issue as yet. The HCPC staff stated that they wanted to respond to the staff recommendation.

Healthcare Compliance Packaging Council
Full Membership Meeting
10:00 am – 2:00 pm
December 7, 2004

Speakers

Suzanne Barone	U.S. Consumer Product Safety Commission
Patricia Spinner	Canon Communications

Members and Guests

Walter Berghahn	American Health Packaging
Louis Cosentino	MeadWestvaco Healthcare Packaging
Patrick Dent	EVC Americas, Inc.
Perry Fan	Montesino Associates, LLC
Dieter Feldberg	Perlen Converting
Robert Hartwig	Pester USA
Hubert Keil	Uhlmann Packaging
Sandra Luciano	Honeywell
Charles Mamrak	TestPak
Mark Miller	DuPont Medical Packaging
Kirk Paisley	SolVin, A Division of Solvay Advanced Polymers, LLC
Robert O'Leary	Permalith Plastics
Richard Sury	Alcan Packaging
John Richard	DuPont Medical and Industrial Packaging

Staff

Peter Mayberry	Executive Director
Kathleen Hemming	Associate Director

EXECUTIVE SUMMARY

Under the current Poison Prevention Packaging Act (PPPA) regulations a test failure for child-resistant unit packaging is defined as access by a child to the number of individual units that constitutes an amount that would cause serious injury or access by a child to more than eight units, whichever is less. The U.S. Consumer Product Safety Commission (CPSC) received a petition from the Healthcare Compliance Packaging Council (HCPC), requesting that consideration of the toxicity of the packaged substance be eliminated from the current regulatory definition. The HCPC's position is that unit packaging is safer than reclosable packaging. The HCPC asserts that the current standards for child-resistance for unit packaging are responsible for the limited use of unit packaging and that removing the toxicity criterion from the definition of failure for child-resistance would result in greater usage of unit packaging.

The numerical criterion was established as an addition to the toxicity criterion, to provide the packaging industry with parameters for the development of child-resistant unit packaging. The original PPPA regulations set the numerical criterion at access to more than five units as a failure but the number of units was changed to eight by the FDA in 1973 (38 FR 12738). In doing so, the FDA made it clear that no impact with respect to protecting children would occur since the toxicity criterion would still prevail to assure that children are protected.

The CPSC staff does not agree with the HCPC's assertions regarding the safety of unit packaging. There are many drugs and other household chemicals that are toxic and would cause serious injury or illness to a child if eight or fewer units were consumed or accessed. These include sulfuric acid, oral hypoglycemic drugs, tricyclic antidepressant drugs, and antipsychotic drugs to name a few. If the change the petitioner requested is adopted, children would have no protection from the most toxic products, that is, those that can result in serious injury or serious illness following access to eight or fewer units. This concern was echoed in the comments from various Poison Control Center Directors, Clinical Toxicology Associations, and the American Academy of Pediatrics.

The CPSC staff does not believe that there is adequate information to demonstrate that changing the definition of failure for unit packaging as the petitioner requests will result in greater use of unit packaging or in fewer child poisonings. The Pharmaceutical Research and Manufacturers of America, a major pharmaceutical trade association, stated that its member companies would not knowingly use packaging that was insufficiently protective for children. Furthermore, child-resistant unit packaging providing the most protective levels of child-resistance is technically feasible, practicable, appropriate, and commercially available.

Based on the foregoing information, the CPSC staff recommends that the Commission deny the petition.