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LOG OF MEETING

SUBJECT: Unit Dose Packaging

DATE OF MEETING: April 16, 1996

PLACE: Consumer Product Safety Commission Headquarters, 4330 East West Highway, Bethesda, MD.

LOG ENTRY SOURCE: Suzanne Barone, Ph.D., Project Manager for Poison Prevention, EHPS

SB

COMMISSION REPRESENTATIVE: See attached

NON-COMMISSION REPRESENTATIVE: See attached

SUMMARY OF MEETING:

The CPSC staff invited members of the Healthcare Compliance Packaging Council (HCPC) to meet to discuss the project on unit dose packaging. The agenda is attached.

The staff discussed the "more than eight" restriction for unit packaging in the regulations of the Poison Prevention Packaging Act (PPPA). This was a benchmark for industry. The HCPC and staff members discussed ways to allow more flexibility in packaging drugs that are associated with low toxicity. In addition, the need for protocol test guidelines for was discussed. The complexity of defining failure for unit packaging was also discussed.

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Meeting with HCPC
Jnit Packaging
4/16/96
1:30pm rm 612

ATTENDEES

<u>Name</u>	<u>Company</u>	<u>Telephone</u>
Suzanne Barone	CPSC-EHPS	(301) 504-0477 ex. 1196
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TEWABE ASEBE	CPSC-EHPS	(301) 504-0477 EXT 1379
MARCIA ROBINS	CPSC-ECON	(301) 504-0962 EXT 1329
CAROLYN MEIERS	CPSC-ESHF	(301) 504-0468 x1281
Michael Bogumill	CPSC-CRM	(301) 504-0400 x1368
Susan Aitken	CPSC-EHPS	(301) 504-0477 x1195
Janet Jacobson	Consumer	(301) 365-1071
HARLEIGH EWELL	CPSC/OGC	(301) 504-0980 x 2217
MAUREEN CISLO	PRODUCT SAFETY LETTER	(703) 247-3423
DARLA WILLIAMSON	CMA	(202) 223-9050
DANIEL GERNER	HCPC	215-637-8100
Peter Maybury	HCPC	202-434-4268

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Agenda

1. Current Regulations (effective January 24, 1996)

(ii) *Test failures.* A test failure shall be any child who opens the special packaging or gains access to its contents. In the case of unit packaging, however, a test failure shall be any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower, during the full 10 minutes of testing. The number of units that a child opens or gains access to is interpreted as the individual units from which the product has been or can be removed in whole or in part. The determination of the amount of a substance that may produce serious personal injury or serious illness shall be based on a 25-pound (11.4 kg) child. Manufacturers or packagers intending to use unit packaging for a substance requiring special packaging are requested to submit such toxicological data to the Commission's Office of Compliance.

2. Issues

- A. Flexibility for packaging products that are less toxic (over the 8 limit).
- B. Guidelines for unit packaging test procedures.
- C. Definition of failure

3. Questions for HCPC

- A. What regulatory changes would the HCPC like to see?
- B. Do manufacturers and contract packers like having a benchmark (8 units)?
- C. Do contract packers give the range of child-resistance for a unit package types or do drug companies specifically request certain child-resistance (i.e. at 4 unit level)?
- D. How do the drug companies assess what type of unit packaging to use?