LOG OF MEETING

SUBJECT: PPPA Protocol Revisions

DATE OF MEETING: October 20, 1994 2:00 pm

PLACE: CPSC Headquarters, Bethesda, MD. Room 410A.

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

COMMISSION REPRESENTATIVE: See attached list

NON-COMMISSION REPRESENTATIVE: See attached list.

SUMMARY OF MEETING:

Representatives from the CSMA requested a meeting to discuss the issue of the effective date of the proposed changes to the PPPA test protocols. The CPSC staff presented an overview of the options for the effective date and the pros and cons of each approach. The option the staff believes has promise is a one year effective date with the opportunity for companies who experience difficulty meeting the effective date to request extensions. Companies would have to justify and document why additional time is required. This is similar to the approach used for lidocaine and dibucaine. The companies would submit such documentation 9 months after the published date. The staff believes that this approach takes care of the major issues. It allows the most child-resistant senior-friendly packaging to be on the market in the shortest time. Those people who experience problems either expected or unexpected will have the opportunity to request additional time based on their need.

The CSMA representatives expressed concern about the ability of CPSC staff to process requests and the probability of extensions being granted. The CSMA staff requested that consumer products be separated from pharmaceuticals. The CSMA presented a phase-in option. A copy is attached. The CSMA also requested a task force be established. The CPSC staff stated that if the Commission agrees to the approach defined by the CPSC staff, the staff will process the information in a timely fashion. The staff stated that the information for the final rule is scheduled to go to the Commission in December 1994.

CSMA
Rm 410A
2:00pm 10/20/94

Name	Affiliation	Phone #
Suzanne Barone	CPSC-HS	301-504-0477 ex 1196
Charles J. Walbert	CPSC-HS	301-504-0477 ex 1204
David Nelson	S.C. Johnson & Son	414-631-2892
Scott Silvenis	Dow Brands	517-636-4769
Brigid D. Klein	CSMA	202-872-8110
Eileen Moyer	Reckitt & Colman Inc.	201-633-2778
BRYAN R. RUBLE	S.C. JOHNSON & SON	414-631-2443
BARBARA LEIFHEIT	DIAL rep.	414-884-0670
Michele Herrity	L&F Products	(201) 573-5341
Michael Bogumill	CPSC/CERM	301-504-0400 Ex. 1368
Marcia Robins	CPSC/ECON	301-504-0762 x1327
Jerry L. Poissinger	CPSC/EPHA	(301) 504-0470 X1268
Hallerie Ewell	CPSC/OGC	10980 x 2217
Jay Dunkin	CPSC/EC	301 504 0962 x1327

Founded 1914

1913 Eye St. N.W.
Washington, DC 20006

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

202 / 872-8110
Telefax 202 / 872-8114

PHASE-IN OPTION

Because of the difficulty in meeting the statutorily mandated one year effective date, the Consumer Product Safety Commission (CPSC) Staff has asked for suggested phase-in options for the protocol change. In response to this request, the Chemical Specialties Manufacturers Association (CSMA) suggests that the Commission adopt a phase-in approach for Poison Prevention Packaging Act (PPPA) substances, 16 C.F.R. § 1700.14, where it is technically feasible, practicable and appropriate[1], and where confirmed reports based on data from the American Association of Poison Control Centers annual report and NEISS study of children's poisoning incidents support such a change. It is our belief that the proposed CSMA Phase-In approach would address the primary CPSC concerns of maintaining consumer safety, while simultaneously allowing industry to effectively adopt new CPSC testing standards in a thorough yet expedient manner that is technically feasible.

This approach is consistent with the regulations contained in 16 C.F.R. § 1700.3, which require that the Commission consider ". . .(2) available scientific, medical, and engineering data concerning childhood accidental ingestions, illness, and injury caused by household substances; (3) the manufacturing practices of the industries affected by the act; and (4) the nature and use of the household substance."

Based on data obtained through a CSMA Freedom of Information Act Request, it is clear that there is a substantial problem with accidental ingestions of pharmaceutical products. We recommend that pharmaceutical products be regulated concurrently with chemical specialty products currently packaged in HDPE packaging with continuous-threaded closures provided that there are sufficient qualified (i.e., compatible) closures commercially available in

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[1] "Technically feasible" means that package designs that would meet the requirements of 16 C.F.R. § 1700.15(b), and that would be suitable for use with the products subject to the rule, are or can be available. A standard is "practicable" when special packaging for the products covered by the rule is adaptable to modern mass production in assembly line techniques. That special packaging is "appropriate" is established by showing that special packaging can be available in forms that are not detrimental to the integrity of the substance and do not interfere with its storage or use. 55 Federal Register 40658 citing S. Rep. No. 91-345, 91st Cong. 2d Sess. 10 (1970).

sufficient quantities (with pharmaceutical products having priority for the available closure systems.)

In our written comments, and meetings with Commission staff, it was clearly demonstrated that there are certain chemical specialty products that cannot comply with the PPPA protocol revision within one year (technically feasible, practicable and appropriate closure systems do not exist.) For those product forms only, the Commission would not apply the revised senior adult test protocol until it is demonstrated that there are qualified (i.e., technically feasible, practicable and appropriate) closure systems available. CSMA strongly suggests that the Commission establish a voluntary special packaging phase-in task force for assistance in gathering information for ultimate conversion of these difficult closure systems and to advise in future phase-in activities.

Implementation Steps

1. Approve revised protocol (December, 1994).

2. Establish voluntary special packaging phase-in task force.

3. Phase-in implementation - pharmaceutical products and chemical specialty products currently packaged in HDPE packaging with continuous-threaded closures.

4. Keep current adult protocol in effect for those products to be phased-in later.

5. In one year, CPSC will hold a hearing to request information on status of availability of new generation closures that can pass the new senior adult protocol.

6. When a sufficient amount of special packaging for a product class is available, issue final regulation to bring in additional products.

7. Repeat process as necessary.

Justification

1. Complies with statutory requirement of technically feasible, practicable and appropriate.

2. CPSC will have already acted on the protocol change.

3. Provides for orderly phase-in and fairness to avoid having a one year deadline imposed where special packaging is not yet available.

4. Permits testing of closures under a final senior adult test protocol, rather than under a proposed protocol.

5. Accomplishes the Commission's goals.

10/20/94