LOG OF MEETING

SUBJECT: Clinical Trial Packaging

DATE OF MEETING: May 18, 1999

PLACE: CPSC Headquarters, Bethesda, MD

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

COMMISSION REPRESENTATIVES: See attachment.

NON-COMMISSION REPRESENTATIVES: See attachment.

SUMMARY OF MEETING:

Members of the industries that deal with clinical trial testing of new drugs requested this meeting with CPSC staff. This meeting was a follow-up on a staff letter explaining the CPSC position concerning the child-resistance of oral drugs used in clinical trials. A copy of this letter and the meeting agenda are attached.

The industry presented an overview of the clinical trial process to the CPSC staff. This included a discussion of the different phases and the complexity of conducting blind studies. The industry has concerns about the use of child-resistant packaging during phases II and III when titration and crossover studies are conducted. Unit packaging is used for these studies to facilitate patient compliance, especially if multiple drug dosing is conducted. The industry expressed concern that the development of child-resistant unit packaging for these studies is difficult as well as time and cost prohibitive. This packaging is specialized for these trials and may not be used if the product is marketed.

The staff discussed the CPSC concern about sending oral drugs into the home with no child-resistance. The CPSC staff stated that they would develop some guidance for the industry taking into account both the complex issues involved in the clinical trial process and the protection of children.

Meeting with Clinical Interest Group representatives
May 18, 1999
At the CPSC Headquarters, Room 715

Name	Company Name	Telephone Number
Suzanne Barone	CPSC - EHHS	301-504-0477 x 1196
Edward A. Sucz	EPICS	610-889-8774
Mike Dragoon	Clinical Materials Committee - ISPE	607-335-6849
Lori Podkul	Midwest Clinical Supply Group	317-276-1014
Frank J. Tiano	DIA + Contract Packaging	215-501-1201
Marcia Robins	CPSC - ECON	301 504 - [illegible]2
Laura Noble	CPSC	301-504-0400 x1452
Terrase Asebe	CPSC - EHHS	(301) 504-0477 x1279
Marjorie Powell	PhRMA	202 835-3517
Jim Mayberry	Healthcare Compliance Packaging Council	703/847-6727
Carrie Wirsing	Healthcare Compliance Packaging Council	(703) 847-6727
Mike Gidding	CPSC Compliance	301 504 0626
David Berstein (phone)		
Marty Jivens (phone)		
SHARON OLMSTEAD	PhRMA	301-468-5607

Clinical Trials Supply Packaging Issues
May 18, 1999
11:00 am
Room 715

Agenda

I. Introductions

II. Clinical Interest Groups, Purpose, Membership, Functions – Members of the Clinical Interest Group

III. Clinical Trial Process Discussion – Members of the Clinical Interest Group

IV. Clinical Trial Packaging Issues – Members of the Clinical Interest Group

V. Past and Current Practices Used for Clinical Studies – Members of the Clinical Interest Group

VI. Poison Prevention Packaging Act and CPSC Policy – CPSC staff

VII. Open Discussion

VIII. Next Steps

CPSA 6 (b)(1) Cleared
No Mfrs/Prvt Lblrs or Products Identified
Excepted by
Firms Notified,
Comments Processed.

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207-0001

OFFICE OF COMPLIANCE
Chemicals, Clothing, and Household Products Team
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MAR 25 1998

John Siegfried, M.D.
Pharmaceutical Research and Manufacturers of America
1100 15th Street, NW, 9th Floor
Washington, DC 20005

Dear Dr. Siegfried:

The U.S. Consumer Product Safety Commission (CPSC) has responsibility for ensuring that certain products, including prescription medications, are packaged in compliance with the Poison Prevention Packaging Act, 15 U.S.C. §§ 1471-1476, and accompanying regulations found at 16 C.F.R. Part 1700.

Recently, the CPSC staff has been receiving inquiries from drug companies about the need for child-resistant packaging for investigational new drugs (IND). Regulations issued under the PPPA require that drugs for human use intended for oral administration, required to be dispensed by order of a licensed practitioner, and dispensed directly to a patient, must be packaged in child-resistant packaging, unless otherwise directed by the prescriber or requested by the patient. 16 C.F.R. § 1700.14(a)(10). Any investigational new drugs meeting these criteria must be in child-resistant packaging. Therefore, a packager must use child-resistant packaging for oral IND drugs used in out-patient clinical trials.

The requirement for child-resistant packaging would not extend to INDs used exclusively for in-patient clinical trials. The regulations of the PPPA apply to substances which are customarily produced or distributed for consumption, use, or storage in or about the household. 16 C.F.R. § 1700.1(b)(2). The requirement for child-resistant packaging of oral prescription drugs does not extend to those prescribed drugs dispensed for use within institutions such as hospitals and nursing homes. However, any regulated drugs dispensed to patients upon their release for their use at home would be subject to the packaging requirements.

We request that you forward this information to your member companies. If you have questions about the subject of this letter, please feel free to write or call me.

Sincerely,

L.E. Washburn

Laura E. Washburn
Compliance Officer