LOG OF MEETING

SUBJECT: Child-Resistant Packaging

DATE OF MEETING: March 6, 2000

PLACE: Embassy Suites, Burlingame, CA

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

COMMISSION REPRESENTATIVES: Suzanne Barone, HS,

NON-COMMISSION REPRESENTATIVES: PARCS attendees

SUMMARY OF MEETING:

The Pacific Region Clinical Supplies group sponsored a seminar. A copy of the agenda is attached. Suzanne Barone discussed the Poison Prevention Packaging Act (PPPA) regulations for investigational new drugs. A copy of the slides is attached. The CPSC requires child-resistant packaging of investigational drugs under the oral prescription drug rule.

PARCS
Monday, March 6, 2000
Embassy Suites
Burlingame, CA
9:00 a.m. - 5:00 p.m.

Recently, child-resistant packaging regulations were expanded to include clinical trial material packages. The morning session will be devoted to industry, test procedure and CPSC perspectives on this timely subject. In addition, a FDA chemistry reviewer will cover what manufacturing, packaging and testing information the FDA expects to see as part of the CMC section of IND's. Other topics include communication with contractors, cleaning verification studies and techniques to protect perishable clinical supplies.

Introduction to PARCS	David Bernstein Cato Research
Sponsor's Welcome	Monte Maroevich Dow Pharmaceutical
Projections for the Conduct of 21st Century Clinical Trials	Jane Ganter Applied Clinical Trials
Child-Resistant Packaging Test Procedures	Rich Ward Perritt Laboratories
Consumer Product Safety Commission (CPSC) Regulations for the Packaging of Investigational Clinical Supplies	Suzanne Barone US CPSC
Update on Industry Task Force Approach to Compliance with CPSC Regulations	Frank Tiano PCI Clinical Services
Lunch (included in price of meeting)	
FDA Chemistry Reviewer's Expectations for IND Information On Manufacturing, Packaging and Testing of Clinical Supplies	John Simmons US FDA
Getting the Most from Contract Clinical Supply Services	Monte Maroevich Dow Pharmaceuticals
Communication is the Key to Successful Clinical Supply Projects	Bob Whetstone IBAH Pharmaceutics
The Importance of Cleaning Verification Studies When Preparing Clinical Supplies – An Analytical Viewpoint	Frank Santillo ProClinical
Protecting Perishable Clinical Supplies: Selection and Pack-out Using Refrigerants, Dry Ice and Shipping Containers	Lawrence Gordon FDC Packaging

Poison Prevention Packaging Act

Investigational Clinical Supplies

Suzanne Barone, Ph.D.

Consumer Product Safety Commission

Purpose Of PPPA

- To protect children from serious personal injury or serious illness resulting from handing, using or ingesting hazardous household substances.

Investigational Clinical Supplies

- Effective April 16, 1974
- 16 CFR § 1700.14(a)(10)
  - ▲Drugs for Oral Administration
  - ▲Human Use
  - ▲Dispensed by Order of Licensed Practitioner
  - ▲Dispensed to Patient

Exceptions

- Not Used In/Around the Household
  - ▲Institutional Use
    - ➡Hospitals, Nursing Homes
- Exempted from Requirements
  - ▲16 CFR §1700.14(a)(10)(i)-(xx)
- Requested by Patient or Physician
  - ▲15 U.S.C. § 1473(b)

15 U.S.C. § 1473(b)

- "..dispensed pursuant to an order of a physician, dentist, or other, licensed medical practitioner authorized to prescribe, such substance may be dispensed in noncomplying packages only when directed in such order or when requested by the purchaser."

Definition of Package

- 16 CFR § 1700.1(b)(3)
- "Package means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household.."

Special Packaging

- "Packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of substance contained therein within a reasonable time and not difficult for normal adults to use properly.."

Failure for Unit Dose Package

- In the case of unit packaging, 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 units, whichever is lower during the 10 minutes of testing.

Compliance Discretion

- As of June 21, 1999
- Phase II and Phase III Trials ONLY
  - ▲NonCR if no serious illness to child
  - ▲Any CR feature
    - ➡As defined by ASTM D-3475
    - ➡Child-resistant protocol test data
  - ▲Outer Container
    - ➡Meets 16 CFR § 1700.15

Outstanding Issues

- Phase IV Clinical Trials
- Timeline for Compliance

If you have questions about PPPA:

- Call me at 301-504-0477 ex. 1196
- e-mail sbarone@cpsc.gov
- Laura Noble 301-504-0400 ex.1452
- e-mail lnoble@cpsc.gov
- Tewabe Asebe - tasebe@cpsc.gov
- Website www.cpsc.gov