APR 15 1999

CPSA 6 (b)(1) Cleared
No Mfrs/PrvtLblrs or Products Identified
___Excepted by_____
___Firms Notified,
Comments Processed.

LOG OF MEETING

SUBJECT: Child-Resistant Unit Dose Packaging

DATE OF MEETING: March 23, 1999

PLACE: Crowne Plaza Hotel, Philadelphia, PA

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

COMMISSION REPRESENTATIVES: Suzanne Barone

NON-COMMISSION REPRESENTATIVES: See attachment.

SUMMARY OF MEETING:

Suzanne Barone presented a seminar entitled, Child-Resistant Unit Packaging: Testing and Other Issues" at the 7th Annual National Symposium on Patient Compliance sponsored by the Healthcare Compliance Packaging Council. A copy of the handout is attached.

The seminar began with an overview of general Poison Prevention Packaging Act issues including regulated substances and exemptions from the packaging requirements. Child-resistant packaging testing as it relates to unit packaging was discussed. Specific issues included when to give a demonstration, how to present the samples, and when to end the test. The current Commission policy on physician samples and clinical trial drugs was also discussed.

HCPC 7th Annual National Symposium on Patient Compliance
"Compliance Packaging by Sector: Rx Drugs, Clinical Trials, OTC, Nutritionals"
March 23-24, 1999
Crowne Plaza Hotel
Philadelphia, PA

Attendance Listing: By Company

Advent Design Corporation
Dean Hammond*
Tom Lawton*

Alfha Technologics, Inc.
Robert E. Hauser†

algroup wheaton
pharma center shelbyville
Olivier Muggli†

AlliedSignal Inc.
John Blum*
Whitney Erickson
Sandra Luciano
Bill Sharpless

American Association of
Poison Control Centers
Rose Ann G. Soloway†

American Health Packaging
Stephen Maszczak

Anderson Packaging, Inc.
Ed Hancock
Jens Hansen
Mike Kudinski
Dick Williamson*

Bell Technologies
Susan Roth
Dominic Scarfone
Marge Smerak

Biocode
Jeffrey J. Slocum*

Blispak Inc.
James J. Horan

Bosch/TL Systems
Carsten Gruber*
John Van Tol*

Bullwinkel Partners, Ltd.
Eric F. Greenberg†

Covance Pharmaceutical Packaging
Larry Rieg

Dey, L.P.
Susan Dahl

DuPont Pharmacuticals Company
Alison Kayser

F-D-C Reports, Inc.
Jonathan Radow

EVC/Delmar Vinyls
Gene Corcoran
Cynthia MacShane
David Raccagni

Fort James Corporation
Teri Rose

Glaxo Wellcome Inc.
D. Bruce Cohen

Key: * = Exhibitor † = Speaker

H.B. Fuller Company
Craig P. Copping†
Tom Rolando

Harvard Medical School & Brigham & Women's Hospital
Robert Glynn†

Hueck Foils L.L.C.
Brian Erwin*
Jack Oneill*
David Sciubba
George Thibeault*

Jones Packaging Inc.
John Kobal*
Fred Nichols*

Keller & Heckman
George Misko†

Klöckner Pentaplast
Victoria Campbell
Viola Cavallaro
Knud Christiansen
Matt Pickering*
Michael Riley
Kent Sides
John Soporowski*

McNeil Consumer Healthcare
Mark A. Plezia
Scott Shorts

Mebane
Tom Grinnan

Medical Packaging Inc.
George Bartels
Derek Spalter

Medical Technology Systems Inc.
Michael Stevenson

Medirex
Lynn M. Homsky

Milliken Packaging
Eric Knauss
Glenn Mason

Montesino Associates
Peter J. Schmitt†

Nutraceuticals World
TBD*

Ortho-McNeil Pharmaceutical
Susan Germaske
Deborah Harris

Packaging Coordinators, Inc.
Judi Crowe*
Dan Gerner
Gwen Green*
Don Huggins
Renard Jackson

PCI Clinical Services
David Marconi
Elizabeth Gallagher
Frank Tiano†

Pfizer Central Research
Julian Lo

Pfizer Pharmaceuticals
Richard D. Hollander

Pharma Marketletter
Judi Resnick

Pharmaceutical & Medical Packaging News
Daniel Becker*
Howard Revitch*
Patty Spinner*

Key: * = Exhibitor † = Speaker

PharmaDesign Inc.
Matt Coe
Pat Fox

Purdue
Tammy A. Kimball

Pyxis Corp.
Paul Seelinger†

QAD, Inc.
Matt Celona

Quintiles Simirex
Gina DeSantis
Thomas McLoughlin

Reed-Lane, Inc.
Robert H. Case
Rebecca Finck
Helen S. Jacobs
Ron Radwin*
Nancy Warner

Rexam Medical Packaging
Mike Dresen
Alan Pfeil*
Joe Spitz*

Reynolds Metals Company
John Chatillon*
Patrick Dent
Drew John*
Vicki Welch

Sepha Products
Debbie Johnson*
Ernest Parker*

Service Industries, Inc.
John Hopkinson†

Sharp Ivers-Lee
Jim Botkin
Dan Dwyer†
Chuck Kerins*
Tim McBride
Deborah Pyle*

SmithKline Beecham
John Jackson
Jason Vallier

TAP Holdings Inc.
Shari Johnson
Jason Yeske

Tekni-Plex, Inc.
Frank Bieganousky*
Perry Fan*

TestPak, Inc.
Richard J. Krause*

U.S. Consumer Product Safety Commission
Suzanne Barone†

U.S. Food and Drug Administration
Ubrani V. Venkataram†

VersaPharm Incorporated
R. Joe Ware

VPI Mirrex Corporation
Patty Adair*
Kevin Dale
Greg Young*

Warner Lambert
Beth A. Ruland

Key: * = Exhibitor † = Speaker

WEST Pharmaceutical Services
Joseph Clark
Bob Corcoran
Etta D'Ura
Bruce Decker
Karen Flynn
Louise Honey
Paul McAlaine *
Jim Schaal
Thomas Williams*

Westvāco
Shelly Dicken
Scott Johnstone*
Brad Jones
Andy Luke*
Mark Mellon
John Smit

Winpak Portion Packaging
Dick Abbott

Wyeth-Ayerst Laboratories
Susan Curran
Paul Finkelston
Rich Hunsinger
Andrea W. Lee
Jim Pierantozzi

Healthcare Compliance Packaging Council
Staff members:

Peter G. Mayberry, Staff Director
Carrie Wirsing, Staff Consultant

Key: * = Exhibitor † = Speaker

Suzanne Barone, Ph.D.
U.S. Consumer Product Safety Commission

CHILD-RESISTANT UNIT PACKAGING

Suzanne Barone, Ph.D.
Consumer Product Safety Commission

Child-Resistant Unit Packaging Issues

- General PPPA Issues
- Test methods for Unit Packaging
- Definition of "failure"
- Over-packaging
- Physician Samples
- Clinical Trials

General PPPA Issues

- Substances 16 CFR § 1700.14
  - ▲Drugs
    - ➧Aspirin, methyl salicylate, acetaminophen, controlled drugs, oral prescription drugs, iron-containing drugs and dietary supplements, diphenhydramine, ibuprofen, loperamide, lidocaine, dibucaine, naproxen, and ketoprofen
  - ▲Household Chemical Products

Suzanne Barone, Ph.D.
U.S. Consumer Product Safety Commission

Exceptions

- Prescription
  - ▲Bulk Drugs Intended to be Repackaged by the Pharmacist
  - ▲Request by Patient or Physician
- OTC
  - ▲One size - labeled (16 CFR §1700.5) as long as other popular sizes are CR

Child-Resistant Unit Packaging Test Methods

- Senior Test -16 CFR§1700.20(a)(3)
  - ▲100 adults (50-70 years old)
  - ▲5 minute/1 minute test period
    - ➡omit closing commands
  - ▲Open 1 unit each time period
  - ▲90% effectiveness

Child-Resistant Unit Packaging Test Methods

- Child Test - 16 CFR§1700.20(a)(2)
  - ▲Panels of 50 children
  - ▲42-51 months
  - ▲5 minute - demo - 5 minute
    - ➡Use of teeth

Suzanne Barone, Ph.D.
U.S. Consumer Product Safety Commission

Child Test Issues - Unit Packaging

- Presentation of Packages
- Demonstration
- Use of tool
- End of Test?

Failure

- 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.

What is a Package?

- Immediate Container or Wrapper 16 CFR §1700.1(b)(3)
  - ▲Single package = total of all units in "retail package"
  - ▲Over-Packaging

Suzanne Barone, Ph.D.
U.S. Consumer Product Safety Commission

Physician Samples

- Current Position (49 FR 8008)
  - ▲Manufacturer not responsible
  - ▲Physician is responsible
- Reevaluation
  - ▲Starter Kits
  - ▲Toxicity
  - ▲Use

Clinical Trials

- Drug for Oral Administration
- Order of Licensed Practitioner
- Dispensed to Patient
- Out-Patient Trials

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
- Website www.cpsc.gov

CPSA 6 (b)(1) Cleared
No Mfrs/Prvtlblrs or Products Identified
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Comments Processed.

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

OFFICE OF COMPLIANCE
Chemicals, Clothing, and Household Products Team
Fax: 301-504-0359

Laura E. Washburn
Compliance Officer
Tel: 301-504-0400, ext. 1452
e-mail: lwashburn@cpsc.gov

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

reasons, neither an environmental assessment nor an environemental impact statement is required.

Therefore, pursuant to provisions of the Administrative Procedure Act (5 U.S.C. 553) and the Federal Hazardous Substances Act (secs. 3(c), 10(a), 74 Stat. 374, 15 U.S.C. 1262, 1269, as amended), the Consumer Product Safety Commission proposes that section 1500.84 of Title 16, Chapter II, Subchapter C of the Code of Federal Regulations be revoked, removed, and reserved.

All interested parties are invited to submit written comments on this proposal to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. Comments must be received no later then April 4, 1984, and received comments may be seen in the Office of the Secretary, 8th Floor, 1111 18th Street NW., Washington, D.C., during normal working hours.

Effective date: The revocation is proposed to become effective 30 days after it is published in final form in the Federal Register.

Authority: 5 U.S.C. 553; 15 U.S.C. 1262, 1269.

List of Subjects in 16 CFR Part 1500

Consumer protection, labeling, exemptions.

Dated: February 28, 1984.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 84-5773 Filed 3-2-84; 8:45 am]

BILLING CODE 6355-01-M

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16 CFR Part 1701

Prescription Drugs Distributed To Prescribing Practitioners; Withdrawal of Proposed Statement of Policy and Interpretation

AGENCY: Consumer Product Safety Commission.

ACTION: Withdrawal of proposed rule.

SUMMARY: The Consumer Product Safety Commission withdraws a proposed rule that would have required all prescription drugs that are subject to a child-resistant packaging standard and that are distributed to physicians and other prescribing practitioners to be in child-resistant packaging if the immediate packages in which the drugs are distributed by the manufacturer are intended to be the packages in which the drugs are dispensed to the consumer. The proposal is being withdrawn because the Commission lacks data concerning the costs and benefits of such a rule and the available data are not sufficient to establish the portion of reported ingestions that may involve drugs being distributed by practitioners in packaging that is not child-resistant.

DATE: The withdrawal of the proposal is effective March 5, 1984.

FOR FURTHER INFORMATION CONTACT: Charles M. Jacobson, Directorate for Compliance and Administrative Litigation, Consumer Product Safety Commission, Washington, D.C. 20207, phone (301) 492-6400.

SUPPLEMENTARY INFORMATION: Section 3 of the Poison Prevention Packaging Act of 1970 ("the act"), 15 U.S.C. 1472, authorizes the establishment of standards requiring "special packaging" for certain household substances in order to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances. "Special packaging" is packaging that is designed or constructed to be (1) significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and (2) not difficult for normal adults to use properly (15 U.S.C. 1471(4)). A household substance is one which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household.

In the Federal Register April 16, 1973 (38 FR 9431, 9432), a regulation (now 16 CFR 1700.14(a)(1)) was issued that requires that all oral prescription human drugs be supplied in special packaging.

The Commission's policies concerning the manufacturer's distribution of prescription drugs in noncomplying packaging intended for consumer use have been different, depending on whether the manufacturer distributed the drug to a pharmacy or to a prescribing practitioner. The Commission has codified a statement (16 CFR 1701.1) of its long-standing policy that when prescription drugs are distributed by manufacturers to pharmacies in packages that are intended to be dispensed directly to consumers, all immediate containers of such drugs must meet the standards for special packaging. Whether a manufacturer intends that a package will be the one in which the drugs are dispensed to the consumer can be determined from the type of package, whether the ancillary instructions provided on the package (such as for storage or handling) are intended for consumers, and other factors.

However, the previous policy of the Commission, and of the Food and Drug Administration which preceded the Commission in administering the Poison Prevention Packaging Act of 1970, was that such drugs could be distributed to prescribing practitioners in either complying or noncomplying packaging. The reason that this policy was followed in the past was that since, under section 4(b) of the act, the prescribing practitioner has the discretion to prescribe drugs for consumers in noncomplying packaging, there was no apparent need to require that the drug be distributed to the practitioner in complying packaging. The policy of not requiring drugs subject to child-resistant packaging standards to be in child-resistant packaging when consumer packages of such drugs are distributed to physicians or other prescribing practitioners has been the subject of much debate over the years. A strong argument can be made that the opposite interpretation is more consistent with the terms of the PPPA. The legislative history of the act shows that it was the intent of the act for special packaging to be the rule and not the exception. Futhermore, it seems that the practitioners would be more likely to dispense these drugs in child-resistant packaging if that were the form of packaging supplied to the practitioner. For these reasons, the Commission previously proposed to change its policy so that manufacturers of these drugs would be required to package them in child-resistant packaging if the drugs were furnished to the practitioner in packages intended to be dispensed to the consumer. 43 FR 12029; March 23, 1978.

The Commission received 15 comments in response to the proposal to change its policy applicable to manufacturers supplying drugs in consumer packages to practitioners. Comments from a university medical center, two pharmaceutical associations, and a pharmacists' association supported the proposed change in policy. The remaining comments, from the Pharmaceutical Manufacturers Association and various pharmaceutical manufacturers, either opposed the issuance of the proposed policy change or suggested modifications to the rule.

In the comments which were received in response to the proposed statement of policy, 2 comments raised the question of whether unit package samples of eight units or less which do not contain an amount of drug which would be harmful to a 25-pound child would automatically comply with the special packaging requirement. The response to these comments is that such packaging would comply.

The vast majority of physicians' samples are packaged in unit packaging.

Unit packaging is packaging in which each dosage unit, e.g., a tablet or a capsule, is individually packaged in such a way as to protect the integrity of the product. A unit package may or may not be attached to other individual unit packages or packaged in an outer carton. The most common types of unit packaging used for physicians' samples are blister packaging or strip packaging.

The protocol for determining the child-resistance of special packaging (16 CFR 1700.20) contains special provisions for defining a package failure for unit packaging. For containers other than unit packaging, a failure occurs when any child opens the special packaging or gains access to its contents during the test. In the case of unit packaging, however, a test failure occurs when any child opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness to a 25-pound child, or to more than 8 individual units, whichever number is lower.

The Commission staff estimates that over 75% of physicians' samples are packaged in unit packaging and that most if not all of this unit packaging would contain not more than 8 individual units. The Commission's staff also believes that the majority of products distributed as physicians' samples would be of a low enough toxicity that more than 8 units would be required to cause serious injury or illness to a 25-pound child. Therefore, it seems likely that the majority of physicians' samples already comply.

After considering the comments and other available information, the Commission concluded that issuance of the proposed policy at this time is not appropriate because information currently available does not establish that there is a significant risk to young children as a result of present packaging practices for physicians' samples. Furthermore, the Commission lacks data on the costs and benefits of the proposed policy change. Since the Commission lacks data showing that the proposed policy change is needed, the Commission has decided to withdraw the proposal.[1] If information becomes available in the future showing risks to young children associated with physicians dispensing samples without child-resistant packaging, the Commission at that time could propose an appropriate policy change based on the new information.

The Commission would also like to point out that, regardless of the type of packaging supplied to the practitioner by the sample manufacturer, the PPPA establishes that a dispensing practitioner is responsible for placing drugs they supply to consumers in child-resistant packaging unless the practitioner decides that child-resistant packaging is not appropriate in a particular case. The Commission believes that the purpose of 15 U.S.C. 1473(b), which allows medical practitioners to order that prescribed substances subject to PPPA requirements be dispensed in noncomplying packaging, is to allow practitioners to see that persons, such as the elderly and handicapped, who cannnot use substances in complying packaging, can have these substances in non-complying packaging.

Conclusion

Therefore, for the reasons explained above, the Commission withdraws the proposal of March 23, 1978 (43 FR 12029) to issue a new § 1701.2 in title 16 of the CFR.

List of Subjects in 16 CFR Part 1701

Consumer protection, Hazardous materials, Infants and children, Packaging and containers, Poison prevention, and Prescription drugs.

Dated: February 28, 1984.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 84-5772 Filed 3-2-84; 8:45 am]

BILLING CODE 6355-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 4 and 12

[Docket No. RM83-56-000]

Application for License, Permit, and Exemption From Licensing for Water Power Projects

Issued: February 24, 1984.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is proposing to amend its regulations governing applications for license, preliminary permit, and exemption from licensing for hydroelectric projects. This rulemaking would: (1) Clarify and revise many of the Commission's regulations that govern hydroelectric applications; (2) amend 18 CFR Part 4 to incorporate Commission decisions into these regulations; and (3) reorganize several sections of 18 CFR Part 4 to integrate the regulations governing exemption applications into Subpart D of 18 CFR Part 4.

DATES: Comments must be in writing and received by the Secretary of the Commission by May 4, 1984.

ADDRESSES: All filings should refer to Docket No. RM83-56-000 and should be addressed to: Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Joseph H. Long, Division of Rulemaking and Legislative Analysis, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, (202) 357-8033.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Federal Energy Regulatory Commission (Commission) proposes to amend its regulations governing applications for license, preliminary permit, and exemption from licensing for hydroelectric projects. This rulemaking would accomplish three major objectives. First, it would clarify and revise many of the Commission's regulations that govern hydroelectric applications, which are set forth in 18 CFR Part 4. Second, it would amend Part 4 to incorporate Commission decisions into the regulations. Third, it would reorganize several sections of Part 4 to integrate the regulations governing exemption applications into Subpart D of Part 4. Subpart D prescribes the general procedural rules for filing applications, the rules of competition, and the rules for selection among competing applications.

The rule would revise §§ 4.30 through 4.35, 4.40, 4.41, 4.50, 4.51, 4.60, 4.61, 4.70, 4.71, 4.80 through 4.83, 4.90 through 4.94, 4.101 through 4.107, and 4.201. It would add new §§ 4.36, 4.37, 4.38, 4.84, 4.95, and 4.96.

II. Background

During the past six years, the Commission has undertaken a broad program of promulgating new rules amending most of its regulations governing hydroelectric applications. The Commission did this (1) to implement new Congressionally mandated programs exempting certain

[1] The withdrawal notice was approved by Chairman Nancy Harvey Steorts and Commissioners Stuart M. Statler and Terrence M. Scanlon. Commissioner Saundra B. Armstrong, who was not a member of the Commission when this matter was previously considered, abstained from voting on it.