UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

2001 DEC 10 A 8:02

BALLOT VOTE SHEET
TIME CRITICAL MATTER

DATE: DEC - 7 2001

TO: The Commission
Todd A. Stevenson, Secretary

THRU: Thomas W. Murr, Jr., Acting Executive Director TM
Jacqueline Elder, Acting Assistant Executive Director, Office of Hazard Identification and Reduction JE

FROM: Alan C. Shakin, Acting General Counsel ACS
Stephen Lemberg, Assistant General Counsel SL
Lowell F. Martin, Attorney-Advisor LFM

SUBJECT: Technical Amendment to Regulation Requiring Child-Resistant Packaging for Certain Over-The-Counter Oral Drug Products

Time Critical Matter
Ballot Vote Due: DEC 14, 2001

On August 2, 2001, the Commission issued a final rule, copy attached, to require child-resistant packaging for oral drug products granted over-the-counter (OTC) status by the Food and Drug Administration that contain one or more previously prescription only active ingredients. 66 FR 40111. The rule was issued under authority of the Poison Prevention Packaging Act (PPPA), 15 U.S.C. 1471-1476.

CPSC staff is now aware of confusion in the regulated community concerning the intended scope of the rule. The regulation as proposed and as issued in final form was intended to apply only to an OTC oral drug product containing a previously prescription-only oral active ingredient first granted OTC status as a result of an application submitted to the FDA on or after the January 29, 2002 effective date of the final OTC-switch rule.

Nevertheless, the August 2, 2001 rule can be read to require CR packaging of an oral drug product approved for OTC switch after the rule becomes effective, even if that drug product contains only active ingredients for which an application for OTC switch was submitted to the FDA by some manufacturer prior to the effective date. The CR packaging requirement of the rule can also be interpreted to be triggered by non prescription-only active ingredients in previously prescription-only drug products. This was not the intent of the rule. If it were to operate in this fashion, it could conceivably provide an unfair competitive advantage to a

FDA 6 (b)(1) cleared
No Mfrs/Prvt Lblrs or Products Identified 12/7/01

NOTE: This document has not been reviewed or accepted by the Commission 12/7/01

manufacturer who submitted an application for OTC switch prior to the effective date over a manufacturer of a subsequently switched drug containing solely the same active ingredients.

The attached draft *Federal Register* notice would clarify these points.

Because it is a technical correction that does not alter the intended scope of the rule or otherwise widen its applicability, OGC recommends that the Commission find that good cause exists to issue the technical amendment as a direct final rule. 5 U.S.C. 553(b)(3)(B).

If the *Federal Register* notice is received by the office of the Federal Register on or before December 17, 2001, the clarifying amendment will be incorporated into the January 1, 2002 revision to the bound Code of Federal Regulations volume including the regulations of the Commission.

If received by the Office of the Federal Register on or before December 17, the notice should be published in the *Federal Register* sooner than 30 days before its January 29, 2002 effective date. However, there is a possibility that it would appear in the *Federal Register* less than thirty days before the effective date. To address that possibility, the attached draft *Federal Register* notice includes an optional paragraph whereby the Commission would waive the 30 day effective date otherwise required by section 553(d) of the Administrative Procedure Act, if necessary. OGC recommends that the Commission give the acting General Counsel discretion to include that paragraph in the version of the notice sent to the Office of the Federal Register, if required.

Please indicate your vote on the following options.

I. Issue the *Federal Register* notice as drafted and give the acting General Counsel discretion to include the 30 day effective date waiver paragraph, if necessary.

_____ _____

(Signature) (Date)

II. Issue the *Federal Register* notice with the following changes and give the acting General Counsel discretion to include the 30 day effective date waiver paragraph, if necessary.

_____

_____

_____

_____ _____

(Signature) (Date)

III. Do not issue the *Federal Register* notice.

_____ _____

(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____

(Signature) (Date)

Attachments

by the Commission on February 8, 1994 (59 FR 5699).

Manufacturers of heat pump water heaters must continue to use the ranges that were published on September 1, 2000 (65 FR 53163). Manufacturers of heat pump water heaters must continue to base the disclosures of estimated annual operating cost required at the bottom of EnergyGuides for these products on the 2000 Representative Average Unit Costs of Energy for electricity (8.03 cents per kiloWatt-hour) that were published by DOE on March 8, 2001 (66 FR 27856), and by the Commission on May 21, 2001 (66 FR 27856).

Manufacturers of gas-fired instantaneous water heaters must continue to use the ranges of comparability that were published on December 20, 1999 (64 FR 71019). They must continue to base the disclosures of estimated annual operating cost required at the bottom of EnergyGuides for these products on the 1999 Representative Average Unit Cost of Energy for natural gas (68.8 cents per therm) and propane (77 cents per gallon) that were published by DOE on January 5, 1999 (64 FR 487) and by the Commission on February 17, 1999 (64 FR 7783).

Manufacturers of pool heaters must continue to use the ranges that were published on August 21, 1995 (60 FR 43367). Manufacturers of room air conditioners must continue to use the corrected ranges for room air conditioners that were published on November 13, 1995 (60 FR 56945, at 56949). Manufacturers of pool heaters and room air conditioners must continue to base the disclosures of estimated annual operating cost required at the bottom of EnergyGuides for these products on the 1995 Representative Average Unit Costs of Energy for electricity (8.67 cents per kiloWatt-hour), natural gas (63 cents per therm), propane (98.5 cents per gallon), and/or heating oil ($1.008 per gallon) that were published by DOE on January 5, 1995 (60 FR 1773), and by the Commission on February 17, 1995 (60 FR 9295).

For up-to-date tables showing current range and cost information for all covered appliances, see the Commission's Appliance Labeling Rule web page at *www.ftc.gov/appliances*.

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

The authority citation for Part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 01–19339 Filed 8–1–01; 8:45 am]

BILLING CODE 6750–01–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Child-Resistant Packaging for Certain Over-The-Counter Drug Products

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: Pursuant to its 3–0 vote to do so, the Consumer Product Safety Commission (CPSC or Commission) is issuing a rule to require child-resistant (CR) packaging on drugs (OTC switched drugs) approved by the Food and Drug Administration (FDA) for over-the-counter (OTC) sale that contain active ingredients previously available only in prescription drugs. Current Commission regulations require CR packaging for most oral drug products containing prescription-only active ingredients. However, prior to issuance of this rule there was no general requirement to maintain CR packaging of such drug products in forms subsequently approved by the FDA for OTC sale.

The Commission is also revoking the current prohibition on granting a petition for an exemption from a CR packaging requirement prior to FDA approval of the drug product in question.

The Commission takes these actions under authority of the Poison Prevention Packaging Act of 1970, as amended.

DATES: The rule will become effective on January 29, 2002, and applies only to products for which the new drug application (NDA) or abbreviated new drug application (ANDA) for the OTC switch is submitted to the FDA on or after that date.

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Ph.D., Directorate for Health Sciences, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0477 ext. 1196 or Geri Smith, Office of Compliance, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0608 ext. 1160.

SUPPLEMENTARY INFORMATION:

A. Background

1. Prior Regulatory Approach

The Poison Prevention Packaging Act of 1970 (PPPA), 15 U.S.C. 1471–1476, was established to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting hazardous substances. Under the PPPA, the CPSC can require child-resistant packaging of hazardous household chemicals, including drugs. The CPSC currently requires child-resistant packaging of oral prescription medications, unless they have been specifically exempted from the packaging requirements. 16 CFR 1700.14(a)(10). In contrast, OTC drugs, which are also called nonprescription drugs because they can be sold to consumers without prescription by a licensed medical practitioner, have not previously been regulated as a class under the PPPA.

Regulations have been issued to require child-resistant packaging of several individual OTC products including diphenhydramine, ibuprofen, loperamide, naproxen, and ketoprofen. These oral drugs were available originally only by prescription and therefore required child-resistant packaging under the oral prescription drug regulation. The FDA subsequently granted OTC status to these drugs, thus removing them from the scope of the child-resistant packaging requirements of the oral prescription drug regulation. After each of these substances was granted OTC status, the Commission promulgated a separate regulation to require the child-resistant packaging of the drug.

2. Relevant Statutory and Regulatory Provisions

The PPPA authorizes the Commission to establish standards for the "special packaging" of any household substance if: (1) The degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and (2) the special packaging is technically feasible, practicable, and appropriate for such substance. 15 U.S.C. 1472(a).

CR or "special" packaging must be designed or constructed to be: (1) Significantly difficult for children under 5 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). Household substances for which the Commission may require CR packaging include (among other categories) foods, drugs, or cosmetics as these terms are defined in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321. 15 U.S.C. 1471(2)(B). The Commission has promulgated performance requirements for special packaging. 16 CFR 1700.15 and 1700.20.

Section 4(a) of the PPPA, 15 U.S.C. 1473(a), allows the manufacturer or packer to package a nonprescription product subject to special packaging standards in one size of non-CR packaging only if the manufacturer (or packer) also supplies the product in a CR package of a popular size, and the non-CR package bears conspicuous labeling stating "This package for households without young children." 15 U.S.C. 1473(a), 16 CFR 1700.5.

3. The Proposed Rule

On August 30, 2000, the Commission issued a notice of proposed rulemaking (NPR) that would require that CR packaging requirements applicable to an oral prescription drug product continue to apply when that drug product or any other drug product containing an active ingredient of that product is granted OTC status by the FDA. 65 FR 52678. The proposed rule would require that the new use or new dose be sold in CR packaging even if the new use or dose was not approved when the drug product was only available by prescription. This is consistent with the current regulatory approach for a new use for an oral OTC product that is already subject to a CR packaging requirement.

The proposed rule would not extend CR packaging requirements to OTC-switched products that are not oral formulations, even if they contain any of the same active ingredients as an oral preparation.

The proposed rule would require CR packaging for any OTC oral drug product containing an active ingredient that was available by prescription even if the OTC dosage is lower than the prescription strength. This recognizes the reality that absent CR packaging, the "dose" potentially available to a child is the entire package contents.

4. Exemptions

An exemption procedure exists for PPPA-regulated products that do not pose a risk of serious injury or illness to children or for which CR packaging is not technically feasible, practicable, or appropriate. 16 CFR part 1702. Under the proposed rule, this exemption procedure would remain available to manufacturers of OTC-switched products.

The proposed rule would revoke 16 CFR 1702.16(b) so that exemption petitions can be submitted and considered by the Commission earlier in the process, *i.e.*, before FDA approval. This would enable manufacturers to seek an exemption from the CR packaging requirements and have a Commission decision prior to submitting an application to the FDA for approval of an OTC or prescription drug product.

To assist consumers and industry in identifying which OTC-switched drug products require CR packaging, the preamble to the proposal indicated that the Commission intended to maintain a list of OTC-switched drug products subject to the regulation as an appendix to the regulations at 16 CFR 1700.14.

B. Response to Comments

Five comments were received in response to the NPR. Three of the five comments received supported the rule as proposed (CP01–1, 2, 5).

Comment: Several commenters questioned whether the PPPA permits imposing child-resistant packaging requirements on a category of drugs and then placing the burden on a manufacturer to seek exemption of individual drugs. (CP01–1–3, 4)

Response: The PPPA authorizes regulation of a category of substances where the required findings can be made for that category. In fact, a number of entries under the CPSC regulation imposing the PPPA child-resistant packaging requirement, 16 CFR 1700.14(a), are defined as broad categories. (See, for example: controlled drugs—"any preparation for human use that consists in whole or in part of any substance subject to control under the Comprehensive Drug Abuse Prevention and Control Act * * *," (16 CFR 1700.14(a)(4); prescription drugs—"any drug for human use that is in a dosage form intended for oral administration * * *," (16 CFR 1700.14(a)(10)).

All members of the class that would be required to be in child-resistant packaging by an OTC-switch rulemaking were previously covered by the PPPA child-resistant packaging requirement for oral prescription drugs (16 CFR 1700.14(a)(10)). The statutory findings for that class were made by the FDA in the 1972–1973 rulemaking that imposed child-resistant packaging on oral prescription drugs. 38 FR 9431 (April 16, 1973).

The ability of a drug to cause serious injury to a child does not change when it is sold OTC. Child-resistant packaging remains technically feasible, practicable, and appropriate for the OTC version, just as was the case when it was required for the prescription formulation. Furthermore, the continued need for child-resistant packaging is not a factor considered by the FDA when making its decision to approve the switch of a drug from prescription to OTC status. Under the OTC-switch rule as proposed, and as issued in final form today, the responsibility/burden on a manufacturer to justify an exemption for an OTC-switched drug via the procedures of 16 CFR 1702 is the same as it was before the drug was switched.

The courts have typically approved the validity of regulatory schemes where a rule addresses a general situation that is too complex for the rule to be appropriate in every instance, but where an exemption procedure is established to deal with special situations. *See, e.g., United States* v. *Allegheny-Ludlum Steel Corp.*, 406 U.S. 742 (1972); *see also Phillips Petroleum Co.* v. *EPA*, 803 F.2d 545, 562 (10th Cir. 1986)(upholding a regulation applying a "generic streamlined approach or procedure" on the grounds of "feasibility and practicality" where the plaintiff argued that the statute required a case-by-case review).

In a case that addressed the Commission's Flammable Fabrics Act regulatory authority, which is analogous to that under the PPPA, the First Circuit affirmed the categorical approach to regulation. *Bunny Bear* v. *Peterson*, 473 F.2d 1002 (1st Cir. 1973). The *Bunny Bear* court also addressed the "burden" issue by stating that when the regulatory agency "plausibly opts for the inclusion of a particular product [in a regulatory scheme], it is not unreasonable to require affected manufacturers to point out with particularity those features which make special treatment [i.e., exemption] necessary." *Bunny Bear* at 1007.

Comment: One commenter requested that OTC products be available in both child-resistant packaging and non child-resistant packaging for the elderly and disabled (CP01–1).

Response: The PPPA provides for the use of both child-resistant and non child-resistant packaging. Section 4 of the Act allows manufacturers to package a product in one size that does not meet the child-resistant packaging standards. 15 U.S.C. 1473. A product so packaged must carry a labeling statement warning that it is not recommended for use in households with young children. There is no requirement that manufacturers have a non child-resistant size.

It is the manufacturer's decision whether or not to market a

noncomplying size. Manufacturers who market one size of their product in non child-resistant packaging must also supply the product in popular-sized packages that are child-resistant. If the manufacturer does not comply with this provision, the Commission can require that the product be packaged exclusively in child-resistant packaging. 15 U.S.C. 1473(c).

Child-resistant packaging has also become more "adult-friendly." In 1995 the Commission issued a revised test method that tests participants aged 50 to 70, rather than 18 to 45 years of age, to ensure that most adults can use child resistant packaging properly. 16 CFR § 1700.20(a)(3)(i).

Comment: One commenter requested that manufacturers and sellers have 18-months advance notice of the effective date of these packaging changes and that they only be implemented for newly manufactured packages (CP01–2).

Response: The packaging regulation as proposed and as issued in final form applies only to a drug granted OTC status as a result of a new drug applications (NDA) or abbreviated new drug application (ANDA) submitted to the FDA on or after the effective date of the final OTC-switch rule. The rule does not affect any product that is approved for OTC sale before that date. The rule does not impact the current production or sale of previously switched products. Therefore the effective date of 180 days after issuance of a final rule should be adequate for companies currently preparing NDA or ANDA submissions requesting OTC status for oral prescriptions.

Comment: One commenter requested that a comprehensive list of affected products and ingredients be made available in advance of the effective date (CP01–2).

Response: The CPSC will publish a list of drugs that are affected by the rule as soon as the Agency becomes aware of them. CPSC will work with the FDA to obtain timely notification of approval of oral prescription drugs that are granted OTC status. No oral prescription drug approved for OTC sale (or for which the NDA or ANDA for an OTC switch was submitted) before the effective date is affected by the rule. The list will include only OTC switched drugs for which the NDA or ANDA was submitted on or after the effective date of the final rule.

Comment: One commenter questioned the efficiency of the proposed rule in saving staff resources because of the resources potentially needed to consider requests for exemptions. The commenter stated that it may be just as efficient to continue the practice of considering the need for child-resistant packaging on a case-by-case basis (CP01–3).

Response: The primary goal of this rulemaking is not to save staff resources but to continue to protect children from serious injury from ingesting oral prescription drugs that are granted OTC status and become widely available. This rule eliminates the potential for newly switched oral OTC drugs to be packaged and sold without child-resistant packaging before a decision concerning the continued need for child-resistant packaging is made by the Commission. Furthermore, these drugs were already required to be in child-resistant packaging in their prior, prescription-only form. Finally, it is worth noting that some companies already voluntarily use child-resistant packaging for their "OTC switched" products.

The staff cannot estimate how many petitions for exemption from the child-resistant packaging requirements the Commission will receive.

Comment: Two commenters requested revisions to the Commission's PPPA regulations that define child-resistant unit packaging (CP01–3, 4).

Response: The child-resistant unit packaging regulations are not part of this rulemaking. Therefore the comment is beyond the scope of this rulemaking. Accordingly, the Commission is not required to respond to it. *See, e.g., American Iron & Steel Institute* v. *EPA*, 886 F.2d 390, 398 (D.C. Cir. 1989), *cert. denied*, 497 U.S. 1003 (1990).

Comment: One commenter requested clarification that the Commission will accept and act on a petition for exemption early in the process, before a NDA or ANDA is submitted to the FDA.

Response: In the preamble to the proposed rule, the Commission stated that, "* * * the Commission is proposing to revoke 16 CFR 1702.16(b) so that exemption petitions can be submitted and considered by the Commission earlier in the process, i.e., before FDA approval. This would enable manufacturers to seek an exemption from the child-resistant packaging requirements and have a Commission decision prior to submitting an application to the FDA for approval of an OTC or prescription drug product." 65 FR 52682. Since 16 CFR 1702.16(b) is revoked by today's rule, there is no longer any restriction on the timing of Commission consideration of a petition for exemption from an otherwise applicable child-resistant packaging requirement.

The exemption process involves rulemaking. This process can be expedited if the manufacturer meets with the CPSC staff to discuss the process before filing a petition for exemption with the Commission as outlined in 16 CFR part 1702.

Comment: One commenter expressed a concern that if a petition is submitted before the NDA is submitted, it could prematurely signal a company's business plans. They believed that a confidential exemption procedure might be necessary but stated the concern that it would not be compatible with the current rulemaking approach to exemptions. (CP01–3)

Response: The commenter is correct that the child-resistant packaging exemption procedure involves public notice and comment. A petitioner must be willing to make toxicity and safety information available for Commission and public review.

There are many factors that a company considers when deciding to pursue OTC status for an oral prescription drug. These may include safety of use and potential misuse, ability of a consumer to self-treat using the medication, or a new market for a drug at the end of its patent, etc. There is much speculation in the press about drugs that may be "switched" based upon these factors. The commenter (Consumer Healthcare Products Association) publishes a list of potential switches that have been named in the trade or popular press.[1] The FDA requested comments and held a public meeting last year to discuss potential OTC drugs.[2] Much of the discussion at the public hearing focused on classes of drugs that may or may not be appropriate for OTC sale.

A manufacturer of an oral prescription drug that is contemplating seeking approval for an OTC switch could request an exemption for the prescription drug. It is the active ingredient itself at a defined level that would then be exempted. Under the rule as proposed, an exempted oral prescription drug would remain exempted from child-resistant packaging when it is granted OTC status. For example, if an oral contraceptive or colestipol were made available OTC, it would not require child-resistant packaging if the OTC preparation met the same conditions as the exempted oral prescription form. (16 CFR 1700.14(a)(10)(iv) and (xv)). A manufacturer would still have the option of petitioning the Commission for exemption after the drug is approved for OTC sale.

[1] Available on the CHPA website: www.chpa-info.org

[2] 65 FR 24704

C. Statutory Considerations

1. Hazard to Children

Before issuing a rule requiring CR packaging, the Commission must find that the degree or nature of the hazard to children in the availability of OTC-switched drug products by reason of their packaging is such that special packaging is required to protect children from serious injury or illness from handling, using, or ingesting the drug products. 15 U.S.C. 1472(a)(1). These statutory findings were made when the rule requiring CR packaging for oral prescription drug products was promulgated in 1973. 38 Fed. Reg. 9431 (April 16, 1973).

OTC-switches did not begin to occur until several years after the 1973 rule requiring CR packaging for oral prescription drug products was promulgated. The first such switches were carried out in response to recommendations resulting from an FDA Advisory Panel's review of over-the-counter drug products.

The need to continue to protect children remains when oral prescription drug products are granted OTC status. As noted previously, a decision by the FDA to grant OTC status for a prescription drug product is not a determination that there is no toxicity to a child if the drug product is accidentally ingested. The active ingredient(s) contained in the drug product have the same toxicity whether in prescription or OTC form. The issue is whether drug products switched to OTC status at a lower dosage than was available by prescription are still hazardous to young children. This is the case since absent CR packaging, the "dose" available to a child can be the entire contents of the OTC product package. The Commission's experiences with ibuprofen and naproxen demonstrate that toxic amounts of the active ingredients are available even when lower dosages are approved for OTC product sale.

Another important consideration is that OTC drug products are more readily available to consumers and therefore more accessible to children than prescription products containing the same active ingredient(s). The Commission concludes that the available data support the finding that maintaining CR packaging is necessary to protect children from serious injury or illness from ingesting oral prescription drug products that have been granted OTC status.

2. Technical Feasibility, Practicability, and Appropriateness

As a prerequisite to a CR packaging rule, the Commission must also find that the special packaging is "technically feasible, practicable, and appropriate." 15 U.S.C. 1472(a)(2). Technical feasibility may be found when technology exists or can be readily developed and implemented by the effective date to produce packaging that conforms to the standards. Practicability means that special packaging complying with the standards can utilize modern mass production and assembly line techniques. Packaging is appropriate when complying packaging will adequately protect the integrity of the active ingredient(s) in the product and not interfere with its intended storage or use. See S. Rep. No. 91–845, at 10 (1970).

In some cases the same packaging can be used for the OTC product as for the prescription product. However, companies must modify the labels since FDA labeling requirements for OTC drug products differ from the labeling requirements for prescription drugs. Also, most companies develop new packaging specifically for the OTC market. Unit dose packaging is popular for the OTC market, especially for drug products such as antihistamines that are sold in limited quantities. Other products containing active ingredients such as the anti-inflammatory compounds ibuprofen and naproxen are sold in bottles. CR designs of this sort of unit and reclosable packaging are commercially available. The change in status of the drug from prescription-only to OTC does not change the availability of the CR packaging in mass-produced quantities, or detract from its ability to maintain the shelf life of switched drug products. Therefore, the Commission concludes that CR packaging for OTC-switched drug products is technically feasible, practicable, and appropriate.

3. Other Considerations

Section 3(b) of the PPPA requires that the Commission consider the following in establishing a special packaging standard:

a. The reasonableness of the standard;

b. Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

c. The manufacturing practices of industries affected by the PPPA; and

d. The nature and use of the household substance. 15 U.S.C. 1472(b).

The Commission has considered these factors with respect to the various determinations made in this rulemaking, and finds no reason to conclude that the rule is unreasonable or otherwise inappropriate.

D. Applicability

The packaging configuration for a drug product to be switched is determined before a company submits the NDA or the ANDA for the OTC-switch to the FDA. Accordingly, this rule applies prospectively to drug products for which the application for the OTC-switch is submitted to the FDA on or after the effective date of the final rule (180 days after publication).

E. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year after the date such final regulation is issued, except that, for good cause, the Commission may establish an earlier effective date if it determines an earlier date to be in the public interest. 15 U.S.C. 1471n. The NPR proposed an effective date of 180 days after publication of the final rule. The commenter suggesting a further delayed effective date seemed to believe that the proposed rule might apply to an oral prescription drug for which an NDA or ANDA had been submitted to the FDA prior to the effective date or for which the OTC switch had been approved by the FDA prior to the effective date. This is not the case. The rule as proposed and as issued today applies only to drugs for which the NDA or ANDA for the OTC switch is submitted on or after the effective date. Thus the final rule takes effect 180 days after publication.

F. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 *et seq.*, generally requires the agency to prepare initial and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. Section 605 of the RFA provides that an agency is not required to prepare a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared an assessment of the impact of a rule to maintain CR packaging for OTC-switched drug products. A copy of the analysis is available for inspection in

the docket for this rulemaking. The assessment reports that the incremental cost of providing basic CR packaging is usually small ($0.005–$0.02/per package). The assessment notes that the incremental cost may be somewhat higher if the marketer elects to provide more elaborate packaging in an effort to create "shelf appeal" to attract consumers and compete with other OTC products in the same therapeutic category.

Because these costs (if any) are likely to be passed on to consumers, it is unlikely that the rule will have a substantial effect on a significant number of small businesses.

Many previously OTC-switched drug products are already sold in CR packaging. In some instances, for example with certain oral dosage formulations of acetaminophen, ibuprofen and loperamide, this is because the Commission has affirmatively required CR packaging. In other cases, the marketer has elected voluntarily to use CR packaging.

This rule revokes the existing requirement at 16 CFR 1702.16(b) that new drug approval be obtained from the FDA prior to Commission approval of a petition seeking exemption from a CR packaging requirement. Allowing for advance consideration and approval of any legitimate CR packaging exemption petition should minimize or eliminate any unwarranted economic impact that would otherwise result from maintaining the CR packaging requirement on OTC-switched oral prescription drug products or from requiring a change to CR packaging post-marketing.

Based on the foregoing assessment, the Commission certifies that this rule to maintain CR packaging for OTC-switched drug products does not have a significant impact on a substantial number of small businesses or other small entities.

G. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has assessed the possible environmental effects associated with the proposed PPPA requirements for OTC-switched drug products.

The Commission's regulations state that rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(3). Nothing in this rule alters that expectation. Therefore, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

H. Executive Order No. 12,988

As provided for in Executive Order No. 12,988 the CPSC states the preemptive effect of this proposed regulation as follows.

The PPPA provides that, generally, when a special packaging standard issued under the PPPA is in effect, "no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the [PPPA] standard." 15 U.S.C. 1476(a). A State or local standard may be excepted from this preemptive effect if (1) the State or local standard provides a higher degree of protection from the risk of injury or illness than the PPPA standard; and (2) the State or political subdivision applies to the Commission for an exemption from the PPPA's preemption clause and the Commission grants the exemption through procedures specified at 16 CFR part 1061. 15 U.S.C. 1476(c)(1). In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical special packaging requirement that provides a higher degree of protection than the PPPA requirement for a household substance for the Federal, State or local government's own use. 15 U.S.C. 1476(b).

Thus, with the exceptions noted above, this rule preempts non-identical state or local special packaging standards for such drug products.

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Toxic substances, Reporting and recordkeeping requirements.

For the reasons set forth above, the Commission amends 16 CFR part 1700 as follows:

PART 1700—POISON PREVENTION PACKAGING ACT OF 1970 REGULATIONS

1. The authority citation for part 1700 continues to read as follows:

Authority: 15 U.S.C. 1471–76. Secs. 1700.1 and 1700.14 also issued under 15 U.S.C. 2079(a).

2. Section 1700.14 is amended by republishing paragraph (a) introductory text and by adding new paragraph (a)(30) to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) Substances. The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a) is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

(30) *Over-the-Counter Drug Products.* (i) Any over-the-counter drug product in a dosage form intended for oral administration that contains an active ingredient also contained in a drug product that is or was a prescription drug product required by paragraph (a)(10) to be in special packaging shall be packaged in accordance with the provisions of § 1700.15(a),(b), and (c). This requirement applies whether or not the amount of the active ingredient in the over-the-counter drug product is different from the amount of that active ingredient in the prescription drug product. This requirement does not apply to a drug product for which an application for over-the-counter marketing has been submitted to the FDA before January 29, 2002 or which has been granted over-the-counter status by the FDA before January 29, 2002. Notwithstanding the foregoing, any special packaging requirement under this section 1700.14 otherwise applicable to an over-the-counter drug product remains in effect.

(ii) For purposes of this paragraph (30), *active ingredient* means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of humans; and *drug product* means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance (active ingredient), generally, but not necessarily, in association with one or more other ingredients. (These terms are intended to have the meanings assigned to them in the regulations of the Food and Drug Administration appearing at 21 CFR 201.66 (2001) and 21 CFR 314.3 (2000), respectively.)

3. Section 1702.16 is amended by removing paragraph (b) thereof in its entirety.

Dated: July 27, 2001.

Todd A. Stevenson,

Acting Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. *Briefing memorandum from Suzanne* Barone, Ph.D., EH, to the Commission, "Final Rule to Require Special Packaging for Oral Prescription Drugs that are Granted Over-the-Counter Status by the Food and Drug Administration," July 2, 2001.
2. Letter from Debra L. Bowen, M.D., Acting Director, Division of Over-the-Counter Drug Products, Food and Drug Administration, to Jeffrey S. Bromme, Esq., General Counsel, Consumer Product Safety Commission, October 7, 1998.
3. Memorandum from Robert L. Franklin, EC, to Suzanne Barone, Ph.D., EH, "Economic Considerations Related to the Rule to Maintain Child-Resistant Packaging Requirements for Oral Prescription Drugs that Have Been Granted OTC Status by the FDA," May 31, 2001.
4. Memorandum from Suzanne Barone, Ph.D., Project manager for Poison prevention, Directorate for health Sciences, to Sadye E. Dunn, Secretary, Consumer Product Safety Commission, "*Responses to Questions from* Commissioner Moore on Over-the-Counter Switches," June 23, 2000.

[FR Doc. 01–19225 Filed 8–1–01; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01–01–108]

RIN 2115–AE47

Drawbridge Operation Regulations: Jamaica Bay and Connecting Waterways, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary final rule governing the operation of the Belt Parkway Bridge, at mile 0.8, across Mill Basin at Brooklyn, New York. This rule allows the bridge owner to require a one-hour advance notice for bridge openings from 10 p.m. through 5 a.m., Sunday through Thursday, from July 29, 2001 through December 31, 2001. This action is necessary to facilitate structural maintenance at the bridge.

DATES: This temporary final rule is effective from July 29, 2001 through December 31, 2001.

ADDRESSES: Material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–01–108) and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, 6:30 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Schmied, Project Officer, First *Coast Guard District, (212) 668–7165.*

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard has determined that good cause exists under the Administrative Procedure Act (5 U.S.C. 553) *for not publishing a NPRM with* comment and for making this regulation effective in less than 30 days after publication in the **Federal Register**. The Coast Guard believes notice and comment are unnecessary because our review of the bridge logs for the past *two years shows that there have been no* bridge openings requested at night during the time period this rule will be in effect. Making this rule effective less than thirty days after publication is necessary because the bridge owner advised the Coast Guard that emergency *structural maintenance must be* performed to insure safe operation of the bridge. In view of the historic absence of night time bridge opening requests and the demonstrated need to perform structural maintenance, any delay encountered in this regulation's *effective date would be unnecessary and* contrary to the public interest.

Background

The Belt Parkway Bridge, at mile 0.8, across the Mill Basin, has a vertical clearance of 34 feet at mean high water, and 39 feet at mean low water in the closed position. The existing drawbridge operating regulations are listed at 33 CFR 117.795(b).

The bridge owner, New York City Department of Transportation (NYCDOT), requested a temporary regulation to facilitate structural maintenance to replace the deteriorated roadway deck at the bridge.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and *Budget has not reviewed it under that* Order. It is not "significant" under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). This conclusion is based on the fact that there have been no requests to open the bridge during the time period the bridge owner has requested an advance notice requirement.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612) we considered whether this rule would have a significant economic impact on a substantial number of small entities. "Small entities" comprises small businesses, not-for profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This conclusion is based on the fact that there have been no requests to open the bridge during the time period the bridge owner has requested an advance notice requirement.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's *responsiveness to small business. If you* wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal

DRAFT

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Child-Resistant Packaging for Certain Over-The-Counter Drug Products; Correction

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule; correction.

SUMMARY: The Consumer Product Safety Commission (CPSC or Commission) corrects the rule published in the *Federal Register* of August 2, 2001 that requires child-resistant (CR) packaging of certain previously prescription-only oral drug products approved by the Food and Drug Administration (FDA) for over-the-counter (OTC) sale. Drug products that are the subject of the August 2 rule are members of the category known as "OTC switched drug products."

The Commission intended that the August 2 rule apply to an oral drug product that is granted OTC status as the result of an application to switch the product from prescription to OTC status (an OTC switch application) submitted to the FDA on or after the January 29, 2002 effective date of the CPSC rule, except in the following circumstances. The rule was not intended to cover a drug product that contains only active ingredients covered by prior OTC switch applications submitted by the same or any other applicant before the effective date of the CPSC rule. Since publication of the August 2 rule, the Commission has

become aware that a correction is necessary to avoid confusion over this point and is thus issuing a clarifying amendment.

DATE: Effective on January 29, 2002.

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Ph.D., Directorate for Health Sciences, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301)504-0477 ext. 1196 or Geri Smith, Office of Compliance, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301)504-0608 ext. 1160.

SUPPLEMENTARY INFORMATION:

A. The Technical Correction

The Commission published, in the *Federal Register* of August 2, 2001, a regulation to require CR packaging of oral drug products approved by the FDA for OTC sale that contain active ingredients previously available only by prescription. 66 FR 40111. The regulation as proposed and as issued in final form was intended to apply only to an OTC drug product containing one or more previously prescription-only active ingredients first granted OTC status as a result of applications submitted to the FDA on or after the January 29, 2002 effective date of the final OTC-switch rule.

Nevertheless, the August 2, 2001 rule can be read to require CR packaging of a drug product approved for the switch to OTC status after the rule becomes effective on January 29, 2002, even if that drug product contains only an

active ingredient or ingredients for which application(s) for OTC switch were submitted to the FDA by any manufacturer(s) prior to the effective date. The CR packaging requirement of the rule could also be interpreted to be triggered by non-prescription active ingredients in previously prescription-only drug products. This was not the intent of the rule.

The following examples are intended to clarify the scope of the rule as corrected today:

Example 1: Manufacturer A submitted an application to the FDA in December 2001 for OTC switch of an oral drug product containing only prescription-only active ingredient X. Manufacturer A's application is approved by the FDA after the January 29, 2002 effective date of this rule. Manufacturer B submits an application to the FDA in February 2002 for OTC switch of another oral drug product containing only the same active ingredient X.

Neither drug product is subject to this rule. Manufacturer A's drug product is not subject to this rule because the OTC switch application was submitted before the January 29, 2002 effective date. Manufacturer B's drug product is not subject to this rule because it contains only formerly prescription-only active ingredients for which an OTC switch application was submitted to the FDA by some

manufacturer before the effective date of the rule.[1]

Example 2: Manufacturer A submits an application to the FDA in February 2002 for OTC switch of an oral drug product containing prescription-only oral active ingredient X. Active ingredient X is not the subject of an OTC switch application submitted by any manufacturer prior to the January 29, 2002 effective date of this rule.

Manufacturer A's drug product must be in CR packaging under this rule because no application for OTC switch of prescription-only active ingredient X was submitted to the FDA by any manufacturer prior to the January 29, 2002 effective date of the rule.

Example 3: Manufacturer A obtained FDA approval in December 2001 for OTC switch of an oral drug product containing formerly prescription-only active ingredient X. Manufacturer B submits an application to the FDA in February 2002 for OTC switch of an oral drug product containing active ingredient X and prescription-only active ingredient Y. Active ingredient Y is not the subject of any OTC switch application submitted by any manufacturer prior to the effective date of this rule.

Manufacturer A's drug product is not subject to this rule. Manufacturer B's drug product must be in CR packaging under this rule because no OTC switch application for

[1] Of course the situation where the OTC switch application has been submitted to the FDA and also approved prior to the effective date of the CPSC rule is covered by this example.

prescription-only active ingredient Y was submitted to the FDA by any manufacturer prior to the January 29, 2002 effective date of the rule.

Each of these examples pertains only to the scope of this rule. Any other special packaging requirements of 16 CRF 1700.14 otherwise applicable to a drug product remain in full force and effect.

B. The Administrative Procedure Act (APA)

Section 553(b)(3)(B) of the APA authorizes an agency to dispense with certain notice procedures for a rule when it finds "good cause" to do so. 5 U.S.C. 553(b)(3)(B). Specifically, under section 553(b)(3)(B), the requirement for notice and an opportunity to comment does not apply when the agency, for good cause, finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." This amendment does not alter the intended scope of the August 2, 2001 rule or otherwise widen its applicability. Accordingly, the Commission hereby finds that notice of, and public comment on, this technical amendment are unnecessary.

[This paragraph will be included only if the amendment will appear in the *Federal Register* less than 30 days before its January 29, 2002 effective date.] Section 553(d)(3) of the APA authorizes an agency, upon finding good cause, to make a rule effective in less than the otherwise required 30

day minimum. 5 U.S.C. 553(d)(3). This amendment clarifies the scope of the August 2, 2001 rule and does not alter its intended scope or otherwise widen its applicability. Making this amendment effective on the same date as the effective date of the August 2, 2001 rule, that is January 29, 2002, will reduce or eliminate further confusion as to the scope of the rule. Therefore, the Commission hereby finds that good cause exists for making this rule effective in less than the 30 days otherwise required by section 553(d) of the APA.

C. Other Rulemaking Requirements

Because this amendment makes no change in the intended scope or applicability of the August 2, 2001 rule, the Commission hereby incorporates by reference the findings made with respect to it concerning the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, the National Environmental Policy Act, 42 U.S.C.4321, *et seq.*, and Executive Order No. 12988. *See* 66 FR 40114-5 (August 2, 2001).

For the foregoing reasons, the Commission corrects rule FR Doc. 01-19339 published in the *Federal Register* on August 2, 2001, (66 FR 40111) by making the following correcting amendment. On Page 40115, in the third column, revise paragraph (30)(i) to read as follows:

DRAFT

§ 1700.14 Substances requiring special packaging.

(a) * * *

* * * * *

(30) *Over-the-Counter Drug Products.*

(i) Any over-the-counter (OTC) drug product in a dosage form intended for oral administration that contains any active ingredient that was previously available for oral administration only by prescription, and thus was required by paragraph (a)(10) to be in special packaging, shall be packaged in accordance with the provisions of 1700.15(a),(b), and (c). This requirement applies whether or not the amount of that active ingredient in the OTC drug product is different from the amount of that active ingredient in the prescription drug product. This requirement does not apply if the OTC drug product contains only active ingredients of any oral drug product or products for which an application for over-the counter marketing has been submitted to the Food and Drug Administration (FDA) by any entity before January 29, 2002. Notwithstanding the foregoing, any special packaging requirement under this section 1700.14 otherwise applicable to an OTC drug product remains in effect.

* * * * *

Dated: _____

_____
Todd A. Stevenson, Secretary
Consumer Product Safety Commission