activated. Additional review has found that the AFM's of Model 35A and 36A series airplanes also do not contain appropriate flightcrew actions when the cabin altitude aural warning is activated. However, the AFM's do contain an abnormal procedure that allows the flightcrew to troubleshoot the pressurization system prior to donning the oxygen masks after the cabin altitude warning sounds. Troubleshooting may delay donning of the oxygen masks to the point that flightcrews may become incapable of donning their oxygen masks.

The SCR findings indicated that the most likely cause for incapacitation was hypoxia (lack of oxygen). The only other plausible cause of incapacitation is exposure to toxic substances. However, no evidence was found to support the existence of toxic substances.

Delayed response of the flightcrew in donning oxygen masks upon the activation of the cabin altitude warning horn could lead to incapacitation of the flightcrew and loss of control of the airplane.

A review of the emergency procedures in the AFM for Lockheed Model 188A and 188C series airplanes revealed that those AFM's also did not contain the requirement for the flightcrew to immediately don emergency oxygen masks. Therefore, all Lockheed Model 188A and 188C series airplanes may be subject to the same unsafe condition as described above.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require revising the Emergency Procedures Section of the AFM to provide the flightcrew with appropriate and timely actions in response to activation of the cabin altitude warning horn.

Cost Impact

There are approximately 75 Model 188A and 188C series airplanes of the affected design in the worldwide fleet. The FAA estimates that 32 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $1,920, or $60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Lockheed: Docket 2000–NM–265–AD.

Applicability: All Model 188A and 188C series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent incapacitation of the flightcrew and consequent loss of control of the airplane due to delays in donning oxygen masks in response to the activation of the cabin altitude warning horn; accomplish the following:

Revision to the Airplane Flight Manual

(a) Within 90 days after the effective date of this AD, revise the Emergency Procedures Section of the FAA–Approved Airplane Flight Manual (AFM) to include the following. This may be accomplished by inserting a copy of this AD in the AFM.

''Low Cabin Pressure Warning Light Comes On and Horn Starts Blowing

a. Oxygen Masks—Don. Select 100% oxygen.
b. If conditions dictate, initiate emergency descent.
c. Check cabin differential pressure gage.
   1. If differential pressure is below 13.34 + 0.30 in. Hg, lower cabin altitude selector wheel.
   2. If differential pressure is at 13.34 + 0.30 in. Hg, descend to lower aircraft altitude.

Note: Warning horn can be silenced with cabin altitude warning horn switch.''

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Atlanta Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

Note 1: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

Special Flight Permit

(c) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 24, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–22123 Filed 8–29–00; 8:45 am]

BILLING CODE 4910–13–U

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

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

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (CPSC or Commission) is proposing a rule to require child-resistant (CR) packaging on 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, at present, there is no general requirement for CR packaging of such drug products in forms subsequently approved by the FDA for OTC sale.

The Commission is also proposing to revoke 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 Office of the Secretary must receive comments on this proposal on or before November 13, 2000.

ADDRESSES: Mail comments to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or hand deliver them to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814–4408, telephone (301) 504–0800. Comments may also be filed by telefacsimile to (301) 504–0127 or by email to cpsc-os@cpsc.gov.

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Directorate for Health Sciences, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0477 ext. 1196.

SUPPLEMENTARY INFORMATION:

A. Background

1. Current Approach to CR Packaging Requirements

The Poison Prevention Packaging Act, 15 U.S.C. 1471–1476, was enacted to protect children from serious personal injury or illness resulting from handling, using, or ingesting hazardous substances. Under the PPPA the CPSC can require CR packaging of hazardous household chemicals, including drug products. The CPSC regulations currently require CR packaging of all oral prescription drug products that have not been specifically exempted from that requirement. 16 CFR 1700.14(a)(10).

In contrast, OTC drug products, also referred to as nonprescription drug products, are not now regulated as a class under the PPPA. However, a number of specific OTC drug products have been required by Commission regulation to have CR packaging. These drug products and the effective dates of the CR requirements are: (1) Aspirin (1972), (2) liquid methyl salicylate (1972), (3) iron-containing drug products (1978), (4) acetaminophen (1980), (5) diphenhydramine (1984), (6) ibuprofen (1992), (7) loperamide (1993), (8) lidocaine (1996), (9) dibucaine (1996), (10) naproxen (1996), (11) ketoprofen (1997), and (12) minoxidil (1999).

Diphenhydramine, ibuprofen, loperamide, naproxen, and ketoprofen were active ingredients available originally only in oral dose prescription drug products.[1] Drug products containing them therefore required CR packaging under the Commission's general oral prescription drug product CR packaging regulation. The FDA subsequently approved these active ingredients for use in OTC drug products at specific dosage levels. The OTC forms were not subject to the Commission's CR packaging requirement for oral prescription drug products. The CPSC conducted a rulemaking and promulgated a separate regulation to require CR packaging for OTC products containing each of these active ingredients.

2. The Limited Effect of FDA Approval of an OTC-Switch

The FDA approves drug products containing a single active ingredient or a combination of active ingredients for sale in the United States. This includes approval for sale directly to the consumer in OTC product formulations. The primary responsibility of the FDA with respect to OTC drug products is to assure that they are safe and effective when self-administered by a consumer in a proper manner. The FDA does not base granting of OTC status on whether a drug product would be toxic to a child if unintentionally ingested. The FDA confirmed this in a letter to CPSC staff dated October 7, 1998 stating that ''approval of an OTC switch does not in any way imply that FDA has concluded that the product does not continue to need child-resistant packaging.'' A copy of the FDA letter is available in the docket for this rulemaking.

3. Frequency of OTC-Switches

Since 1976, the FDA has permitted many drug products to be sold OTC. According to the Consumer Healthcare Products Association (CHPA) website, ''more than 600 OTC products on the market today use ingredients or dosages available only by prescription just 20 years ago. ''[2] Trade press articles speculate that this trend will continue.[3] The CHPA has compiled a table listing 80 drug products that have been granted OTC status since 1976.[4] Of the 80 listings in the table, 22 are oral drug products that were previously available by prescription. The other listings are topical drug products, new uses, or new formulations for existing OTC drug products, or OTC-approved drug products that were not previously available as prescription products.

The FDA is currently evaluating whether other drug products or drug product categories should be OTC-switched. That agency conducted a two-day public hearing in late June of this year on a spectrum of OTC issues, including OTC switches. In the April 27, 2000 **Federal Register** notice announcing the hearing, 65 FR 24704–6, the FDA stated that it had ''received comments suggesting that a number of other types of drugs should be considered for OTC status.'' The FDA notice indicated that the types of drug products suggested for OTC status include diuretics, antihypertensive agents, cholesterol-lowering drug products, antidiabetic drug products, treatments for osteoporosis, drug products for stomach problems, *etc.*

4. OTC-Switched Drug Products Currently Subject to CR Packaging Requirements

To date, the Commission has required CR packaging for OTC products containing 6 of the 22 oral prescription active ingredients that have also been approved for sale in OTC products. The six active ingredients that currently

[1] The meanings of the terms active ingredient and drug product as used in this rulemaking are the same as the meanings assigned to those terms in the drug product regulations of the FDA. The FDA drug product regulations define active ingredient as ''any component (of a drug product) 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, but does not include intermediates used in the synthesis of such ingredient.'' 21 CFR 201.66 (1999). The FDA regulations define drug product as ''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.'' 21 CFR 314.3 (1999). Drug product also encompasses a product containing more than one active ingredient. 21 CFR 300.50 (1999).

[2] The Uniform Resource Locator (URL) for the CHPA website is: www.ndmainfo.org

[3] Levy, S., Several Prescription Candidates Reported Ripe for OTC Switching, Drug product Topics, November 16, 1998, p.51.

[4] The CHPA Table is available on that organization's website at: www.ndmainfo.org/pdfs/Switch%20List/pdf

require CR packaging in OTC products, the date of OTC approval by the FDA, and the effective date of the CR packaging requirements are listed in Table 1. The other 16 active ingredients are discussed below.

TABLE 1: PRESCRIPTION ACTIVE INGREDIENTS SWITCHED TO OTC STATUS THAT REQUIRE CR PACKAGING

Active ingredient	Year OTC-switched	Year CR packaging effective
Diphenhydramine HCL	1982	1984
Diphenhydramine monocitrate	1982	1985
Ibuprofen	1984	1992
Loperamide	1988	1993
Naproxen sodium	1994	1996
Ketoprofen	1995	1997

5. History of CPSC Regulation of OTC–Switched Oral Drug Products

In the past, CPSC staff focused primarily on ingestion data to recommend to the Commission what products should be in CR packaging. In the late 1970s the FDA allowed the OTC sale of several antihistamines that were previously available only by prescription. Of these, diphenhydramine hydrochloride was the first OTC-switched active ingredient regulated by the CPSC under PPPA authority. Then, in 1982, the FDA approved the monocitrate salt of diphenhydramine for OTC sale. The existing diphenhydramine hydrochloride CR packaging regulation was then amended to cover all diphenhydramine salts.

In 1984, the CPSC staff evaluated ingestion data related to ibuprofen. Products containing ibuprofen were granted OTC status during that year. At that time, the poisoning data were limited and Commission staff did not recommend CR packaging. The two companies that first marketed OTC ibuprofen products used CR packaging voluntarily on some package sizes.

In 1989, CPSC staff revisited ibuprofen toxicity because ibuprofen had become widely available. Not all companies were using CR packaging and serious injuries to children resulted. The Commission issued a rule requiring CR packaging for all of these products. 16 CFR 1700.14(a)(20). Companies that had been marketing their products in non-CR packaging changed their packaging accordingly.

The experience with diphenhydramine and ibuprofen resulted in a change in the staff's approach to recommendations for CR packaging for OTC-switched products. Rather than wait for deaths or injuries to children, Commission staff has become more proactive in recommending CR packaging requirements for OTC drug products. For the past several years the staff has focused on the potential toxicity of active ingredients contained in drug products that are going to be switched instead of waiting for poisonings to occur after a product is released and marketed for OTC sale. The staff has made the evaluation of potential switched drug products the first priority. As a result, separate regulations for products containing loperamide, naproxen, and ketoprofen were promulgated by the Commission soon after OTC status for products containing each of these active ingredients was granted by the FDA.

CPSC staff monitors FDA's activities concerning approval of switched OTC drug products. The staff attends FDA advisory panel meetings when possible, to better understand any issues about a potential switch and the likelihood of approval of OTC status by the FDA. The FDA is not bound to accept the panel's recommendations regarding OTC switches, though in most cases the FDA does. The review of the potential toxicity to young children of the active ingredient or ingredients in the product then becomes a priority for the CPSC staff.

To avoid expending the CPSC's limited resources if the FDA does not approve OTC sale of the drug product, Commission staff waits for FDA approval before proceeding with a review. The proposed rule would eliminate this lag between FDA approval of an OTC-switch and the CPSC requirement to maintain CR packaging.

The 16 oral prescription active ingredients that were switched to OTC status and are not currently required to have CR packaging are pseudoephedrine HCL, pseudoephedrine sulfate, phenylpropanolamine HCL, clemastine fumarate, brompheniramine maleate, chlorpheniramine maleate, dexbrompheniramine maleate, triprolidine HCL, dexchlorpheniramine maleate, doxylamine succinate, pyrantel pamoate, chlophedianol HCL, famotidine, cimetidine, ranitidine, and nizatidine. In conjunction with this rulemaking, CPSC staff has preliminarily assessed the toxicity of eight of these. Based on their toxicity, the staff would recommend CR packaging for drug products containing pseudoephedrine HCL, pseudoephedrine sulfate, phenylpropanolamine HCL, and clemastine fumarate.

The four active ingredients for which the CPSC staff would not recommend CR packaging are members of the same family of antihistamines used to reduce stomach acid. These are famotidine, cimetidine, ranitidine, and nizatidine. These substances do not have the degree of toxicity associated with antihistamines used to treat cold symptoms.

Five antihistamine active ingredients that are currently under preliminary review by Commission staff are brompheniramine maleate, chlorpheniramine maleate, dexbrompheniramine maleate, triprolidine HCL, and dexchlorpheniramine maleate. These antihistamines are related in structure and activity to diphenhydramine, which is currently subject to a CR packaging requirement.

This rulemaking proposal would not retrospectively require CR packaging of FDA-approved drug products containing the 16 OTC-switched active ingredients not currently subject to CR packaging requirements. CPSC staff continues to evaluate these substances as time and other priorities permit. Many drug products containing these active ingredients are in CR packaging because they contain other active ingredients that require CR packaging, for example pseudoephedrine with ibuprofen or an antihistamine with acetaminophen or aspirin. In addition, the Commission is aware of some OTC products that are voluntarily marketed in CR packaging.

B. Relevant Statutory and Regulatory Provisions

The Poison Prevention Packaging Act 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 CR packages 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.

C. The Proposed Rule

1. General Approach

The Commission is proposing a rule to require that CR packaging requirements applicable to any 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. This rule will provide children with the same protection when a drug product is more widely available as an OTC preparation that they had when it was available only by prescription. The rule would eliminate the possibility of a drug product being available in non-CR packaging for an extended time before the CR packaging requirement is reimposed by Commission rulemaking. The need to continue to protect children does not diminish when an oral prescription drug product is granted OTC status. As noted above, a decision by the FDA to grant OTC status for a prescription drug product does not include a finding that there is a lack of toxicity to a child if the drug product is accidentally ingested in an unpredictable amount, which could be the entire contents of the OTC product package. The active ingredient(s) in the drug product still have the same toxicity, whether the drug product is in prescription or OTC form.

2. Additional Uses, Forms, and Combinations of OTC-Switched Drug Products

The FDA can approve a new usage or a new dosage form of a previously-approved OTC-switched drug product. 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. For example, after February 11, 1985, any oral product that contained more than the equivalent of 66 mg. of diphenhydramine base was required to be in CR packaging. At that time, diphenhydramine was in OTC sleep aids and hay fever preparations. In 1987, when diphenhydramine was approved by the FDA for OTC sale as an oral antiemetic drug product, no further CPSC regulatory action was necessary. This same focus on the active ingredient itself rather than the approved usage is the approach of the proposed rule. If an oral prescription drug product were granted OTC status by the FDA it would automatically be subject to a CR packaging requirement under the proposed rule. If the FDA then approved another OTC drug product containing some or all of the active ingredients in that drug product, the new drug product would also automatically be subject to the 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. Formulations other than oral, such as topical preparations, or transdermal patches would still be regulated individually and therefore not affected by this proposed rule.

In some cases, after a prescription drug product is approved for OTC sale by the FDA, other forms, dosages, or combinations containing some or all of the active ingredients in that drug product will also be approved for OTC sale. These combinations or forms may not have existed when the drug was available by prescription only. This proposal would cover these situations. For example, loperamide was granted OTC status by the FDA in 1988. In 1993, the CPSC required CR packaging for any oral product that contained more than 0.045 mg of loperamide. In 1997, the FDA approved the combination of loperamide and simethicone in an OTC product. This combination was never a prescription product. However, the combination OTC product is subject to the CR packaging requirement because the loperamide rule is not limited to the original prescription formulation.

3. Change in Dosage Between Prescription and OTC Drugs

The prescription version of a drug product may be available in different dosages, strengths, and forms. However, the FDA may place restrictions on the allowed level of an active ingredient available for use in an OTC drug product. Several different scenarios exist. First, the active ingredient may be sold in an OTC drug product at the lowest prescription dosage. This is true for many OTC-switched drug products, including the antihistamines. Second, the active ingredient may be sold OTC at the prescription strength but with a lower total daily allowable dose. This is the case for OTC loperamide products. Lastly, a lower dosage of the active ingredient may be developed for the OTC drug product. OTC ibuprofen and naproxen are examples.

This proposal 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 is consistent with the approach of the CPSC's oral prescription drug product CR packaging regulation, which applies to all dosages approved by the FDA for prescription sale. This recognizes the reality that absent CR packaging, the ''dose'' potentially available to a child is the entire package contents.

The Commission has issued rules for individual OTC switched drug products that are only available at a lower dose than the prescription strength product. The Commission's experiences with ibuprofen and naproxen demonstrate that toxic amounts of the active ingredients are available from a single OTC product container even at these new lower dosages.

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. Companies petition the Commission to exempt products by submitting data, described in 16 CFR Part 1702, to support a conclusion either that: (1) the drug product will not cause serious injury or illness, or (2) it is not technically possible to develop and produce CR packaging for the drug product. An exemption petition is processed by informal, notice and comment rulemaking. Currently, 18 oral prescription drug products and several OTC formulations of aspirin, acetaminophen, and iron have been exempted from the CR packaging requirements. 16 CFR 1700.14. Under the proposed rule, this exemption procedure would remain available to manufacturers of OTC-switched products.

5. Timing of Exemption Petitions

The Commission's current CR packaging regulations specify that the Commission shall deny an exemption petition if the FDA has not approved the new drug product. 16 CFR 1702.16(b). Therefore,at present, a company seeking an exemption for a newly approved drug product must either market in CR packaging, delay marketing until the Commission acts on the petition, or request a stay of enforcement to allow marketing in non-CR packaging while the Commission considers the petition.

A post-marketing change in packaging of an approved OTC drug product may be more complex for the manufacturer than simply buying different packaging and modifying the packaging equipment. In some cases, the FDA must approve the new packaging before the drug product can be marketed.[5] Stability testing of the product in the new package must be completed and the results approved by the FDA before the product can be marketed in the new package.

Accordingly, the Commission is proposing to revoke 16 C.F.R. 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.

6. Listing of OTC-Switched Drug Products Subject to CR Packaging

To assist consumers and industry in identifying which OTC-switched drug products require CR packaging, the Commission intends to maintain a list of such drug products as an appendix to the regulations at 16 CFR 1700.14. As the FDA approves OTC-switches, the list would be updated periodically by publishing a revised appendix in the **Federal Register**.

D. Findings

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. 9,431.

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 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 CPSC 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.

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 notice, and preliminarily finds no reason to conclude that the rule is unreasonable or otherwise inappropriate.

E. Applicability

The packaging configuration for a drug product to be switched is determined before a company submits the OTC-switch application to the FDA. Accordingly, the Commission is proposing that this rule apply prospectively to drug products for

[5] *Guidance for Industry, Changes to An Approved NDA or ANDA*. Food and Drug Administration, Drug Information Branch, Center for Drug Evaluation and Reserech, November 1999. This document is available on the FDA website at: www.fda.gov/cder/guidance/index.htm

Copies can also be obtained by calling the FDA Drug Information Branch at (301) 827–4573.

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).

F. 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.

CR packaging is currently available commercially for most, if not all, types of oral prescription drug products that would be subject to this rulemaking. Thus, the Commission is proposing that the final rule take effect 180 days after its publication.

G. 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 an 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 a preliminary assessment of the impact of a rule to maintain CR packaging for OTC-switched drug products. A copy of the preliminary 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 also notes that the incremental cost may be somewhat higher if the marketer provides more elaborate packaging in the effort to create ''shelf appeal'' to attract consumers and compete with other OTC products in the same therapeutic category.

At present, the Commission does not have quantitative information on the number of small businesses that might be affected by the OTC-switch proposal. However, the staff assessment concludes that because the incremental cost of CR packaging is minimal, and because these costs (if any) are likely to be passed on to consumers, it is unlikely that the proposal will have a substantial effect on a significant number of small businesses. The Commission requests comment from companies that supply OTC-switched drug products. The Commission is particularly interested in information on the likely effect of this proposed rule on small businesses.

Many OTC-switched drug products are already 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 notice proposes revocation of 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 the rule to maintain CR packaging for OTC-switched drug products, if promulgated in final form as proposed, would not have a significant impact on a substantial number of small businesses or other small entities.

H. 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 proposed 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.

I. Executive Orders

As provided for in Executive Order 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, the proposed rule requiring CR packaging for OTC-switched drug products would preempt non-identical state or local special packaging standards for such drug products.

J. Trade Secret or Proprietary Information

Any person responding to this notice who believes that any information submitted is trade secret or proprietary should specifically identify the exact portions of the document claimed to be confidential. The Commission's staff will receive and handle such information confidentially and in accordance with section 6(a) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2055(a). Such information will not be placed in the public docket for the rulemaking and will not be made available to the public simply upon request. If the Commission receives a request for disclosure of the information or concludes that its disclosure is necessary to discharge the Commission's responsibilities, the Commission will inform the person who submitted the information and provide that person an opportunity to present additional information and views concerning the confidential nature of the information. 16 CFR 1015.18(b) (1999).

The Commission's staff will then make a determination of whether the information is trade secret or proprietary information that cannot be released. That determination will be made in accordance with applicable provisions of the CPSA; the Freedom of Information Act (FOIA), 5 U.S.C. 552b; 18 U.S.C. 1905; the Commission's procedural regulations at 16 CFR part 1015 governing protection and disclosure of information under provisions of FOIA; and relevant judicial interpretations. If the Commission concludes that any part of the information that has been submitted with a claim that the information is a trade secret or proprietary is disclosable, it will notify the person submitting the material in writing and provide at least 10 calendar days from the receipt of the letter to allow for that person to seek judicial relief. 15 U.S.C. 2055(a)(5) and (6); 16 CFR 1015.19(b).

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 proposes to amend 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)(32) 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:

* * * * *

(32) *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) of this section 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 [insert date 180 days after promulgation of final rule] or which has been granted over-the-counter status by the FDA before [insert date 180 days after promulgation of final rule]. Notwithstanding the foregoing, any special packaging requirement under this § 1700.14 otherwise applicable to an over-the-counter drug product remains in effect.

(ii) For purposes of this paragraph (a)(32), 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 and 21 CFR 314.3, respectively.)

§ 1702.16 [Amended]

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

Dated: August 23, 2000.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. Briefing memorandum from Suzanne Barone, Ph.D., EH, to the Commission, ''Proposed Rule to Require Special Packaging for Oral Prescription Drugs that are Granted Over-the-Counter Status by the Food and Drug Administration,'' May 16, 2000.

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 Marcia P. Robins, EC, to Suzanne Barone, Ph.D., EH, ''Economic considerations: Proposal to Maintain Child-Resistant Packaging Requirements for Oral Prescription Drugs that Have Been Granted OTC Status by the FDA,'' April 7, 2000.

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.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 2

[FRL–6860–9]

RIN 2025–AA02

Elimination of Special Treatment for Category of Confidential Business Information: Reproposal

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) published a document in the **Federal Register** on October 25, 1999 (64 FR 57421), proposing to amend its regulations to eliminate the special treatment of a category of confidential business information (CBI). This category of CBI includes comments received from businesses that substantiate their claims of confidentiality for previously submitted information. In response to requests from interested parties, EPA extended the comment period on the proposed rule from December 27, 1999, to January 26, 2000 (64 FR 71366, December 21, 1999). EPA is now reproposing the rule to address some of the comments that it received.

DATES: Comments on this proposed rule must be submitted by October 30, 2000.

ADDRESSES: Send written comments on this proposed rule to Docket Number EC–1999–015, Enforcement and Compliance Docket and Information Center (ECDIC), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Room 4033, Mail Code 2201A, Washington, DC 20460; Phone, 202–564–2614 or 202–564–2119; Fax, 202–501–1011; Email, *docket.oeca@epa.gov.* Documents related to this proposed rule are available for public inspection and viewing by contacting the ECDIC at this same address.

FOR FURTHER INFORMATION CONTACT: Rebecca Moser, Office of Information