AD, that it will take approximately 1 work hour per airplane, per inspection to accomplish the required actions, and that the average labor rate is $60 per work hour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $1,860, or $60 per airplane, per inspection.

The total cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

The regulations adopted herein will not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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 final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

39.13 [Amended]

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

95–07–06 British Aerospace Airbus Limited (Formerly British Aerospace Commercial Aircraft Limited, British Aerospace Aircraft Group): Amendment 39–9188. Docket 94–NM–165–AD.

Applicability: All Model BAC 1–11–200 and –400 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (b) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To ensure the pilot's ability to initiate roll control during critical phases of the flight, accomplish the following:

(a) Within 5 years from the date of installation of the aileron control bearings or within 6 months after the effective date of this AD, whichever occurs later, perform a detailed visual and physical inspection to detect missing or damaged sealing rings, corrosion, or restricted movement of the bearings of the aileron control system, in accordance with the Accomplishment Instructions of British Aerospace Alert Service Bulletin 27–A–PM6023, Issue No. 2, dated November 23, 1992.

(1) If no discrepancies are found, repeat the inspection requirements thereafter at intervals not to exceed 14 months.

(2) If any discrepancy is found, prior to further flight, replace the bearing with a new bearing in accordance with the service bulletin. Repeat the inspection required by this paragraph within 5 years after replacement of the bearings, and thereafter at intervals not to exceed 14 months.

(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, Standardization Branch, FAA, Transport Airplane Directorate, ANM–113. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(c) Special flight permits may be issued in accordance with sections 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.

(d) The inspections and replacement shall be done in accordance with British Aerospace Alert Service Bulletin 27–A–PM6023, Issue No. 2, dated November 23, 1992. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from British Aerospace, Airbus Limited, P.O. Box 77, Bristol BS99 7AR, England. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on May 10, 1995.

Issued in Renton, Washington, on March 29, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–8172 Filed 4–7–95; 8:45 am]

BILLING CODE 4910–13–U

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Requirements for Child-Resistant Packaging; Requirements for Products Containing Lidocaine or Dibucaine

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: Under the Poison Prevention Packaging Act of 1970, the Commission issues a rule requiring child-resistant packaging for products containing more than 5.0 milligrams (mg) of lidocaine in a single package or more than 0.5 mg of dibucaine in a single package. These requirements are issued because the Commission has determined that child-resistant packaging is required to protect children under 5 years of age from serious personal injury and serious illness resulting from ingesting such substances. Lidocaine and dibucaine are used in prescription drugs and over-the-counter drug products that are applied to the skin or mucous membranes to provide an anesthetic effect.

DATE: The rule shall be effective on April 10, 1996 and shall apply to subject products that are packaged on or after that date.[1]

[1] The Commission approved unanimously (3–0) the motion of Chairman Ann Brown to require

FOR FURTHER INFORMATION CONTACT: Michael Bogumill, Division of Regulatory Management, Office of Compliance and Enforcement, Consumer Product Safety Commission, Washington, DC 20207; telephone (301)504–0621 ext. 1368.

SUPPLEMENTARY INFORMATION:

A. Background

Relevant statutes and regulations. The Poison Prevention Packaging Act of 1970 (the ''PPPA''), 15 U.S.C. 1471–1476, 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. Special packaging, also referred to as ''child-resistant packaging,'' is defined as packaging that is (1) designed or constructed to be 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. It does not mean, however, packaging which all such children cannot open, or obtain a toxic or harmful amount from, within a reasonable time.

Under the PPPA, effectiveness standards have been established for special packaging (16 CFR 1700.15), as has a procedure for evaluating its effectiveness (§ 1700.20). Regulations were issued requiring special packaging for a number of household products (§ 1700.14). The findings that the Commission must make in order to issue a standard requiring child-resistant (''CR'') packaging for a product are discussed below in Section E of this notice. For the purposes of the PPPA, the amount of a substance ''in a single package'' that requires the product to be in CR packaging refers to the total amount in a single retail unit of the substance.

One of the categories of products for which CR packaging is required is prescription drugs intended for oral administration to humans, with specified exemptions. 16 CFR 1700.14(a)(10). Drugs that are applied topically (for example, ointments, creams, sprays, suppositories, mouthwash, etc.) are not covered by the oral prescription drug standard. Where prescription drugs are subject to a special packaging standard, section 4(b) of the PPPA allows such products to be sold in non-CR packaging only when (1) directed by the prescribing medical practitioner or (2) requested by the purchaser. 15 U.S.C. 1473(b).

For nonprescription (over-the-counter, or ''OTC'') products subject to special packaging standards, section 4(a) of the PPPA allows the manufacturer or packer to package a single size of the product in non-CR packaging only if (1) the manufacturer (or packer) also supplies the substance in CR packages and (2) the non-CR packages bear conspicuous labeling stating: ''This package for households without young children.'' 15 U.S.C. 1473(a). If the package is too small to accommodate this label statement, the package may bear a label stating: ''Package not child-resistant.'' 16 CFR 1700.5(b). The right of the manufacturer or packer to market a single size of the product in noncomplying packaging under these conditions is termed the ''single-size exemption.''

The Commission may restrict the right to market a single size in noncomplying packaging if the Commission finds that the substance is not also being supplied in popular size packages that comply with the standard. 15 U.S.C. 1473(c). In this case, the Commission may, after giving the manufacturer or packer an opportunity to comply with the purposes of the PPPA and an opportunity for a hearing, order that the substance be packaged exclusively in CR packaging. To issue such an order, the Commission must find that the exclusive use of special packaging is necessary to accomplish the purposes of the PPPA.

Previous Commission activities. [9] [2] In 1985, the Commission's staff reviewed ingestion data for topical prescription drugs to assess the need for CR packaging. Lidocaine, a local anesthetic, was identified as a topical drug that presented a potential ingestion hazard to young children. Local anesthetics are used to produce temporary loss of feeling to a limited area of the body by decreasing the transmission of nerve impulses in that area.

In 1985, many manufacturers of 2-percent viscous prescription lidocaine drugs were voluntarily using CR packaging on products intended to be dispensed directly to the consumer. The Commission directed the staff to pursue voluntary action to address the ingestion hazard presented by lidocaine-containing drugs and to continue to monitor data on topical prescription drugs. In 1986, the staff sent letters to the known manufacturers of 2-percent viscous prescription lidocaine products requesting that the manufacturers (1) use CR packaging on all consumer-ready packages of 2-percent viscous lidocaine products, and (2) label 2-percent viscous lidocaine products intended to be repackaged by the pharmacist to advise the pharmacist to dispense the drug in CR packaging.

In 1990, the staff updated its review of the toxicity of lidocaine. The scope of the review was expanded to include other topical local anesthetics marketed for consumer use, and to include OTC products as well as prescription products. The review showed that two local anesthetics, lidocaine and dibucaine, have caused serious adverse effects, including death, following accidental ingestion by young children.

After considering the available information, the Commission, on August 4, 1992, proposed a CR packaging requirement for products containing (1) more than 5.0 milligrams (mg) of lidocaine in a single package or (2) more than 0.5 mg dibucaine in a single package. 57 Fed. Reg. 34274.

B. Lidocaine

Product forms, dosage and packaging. Lidocaine is an ingredient in a wide variety of preparations used as anesthetics, general antiseptics, and burn remedies, and for skin care. It is used also in preparations meeting the provisions of the Food and Drug Administration's (FDA's) OTC monograph for male genital desensitizing products (57 Fed. Reg. 27654; June 19, 1992; 21 CFR 348). Lidocaine preparations are available as creams, ointments, gels, jellies, viscous

special packaging for all products containing more than .5 mg of dibucaine in a single package. The Commission voted 2–1 to require special packaging for all products containing more than 5 mg of lidocaine in a single package (Chairman Brown and Commissioner Jacqueline Jones-Smith voting for and Commissioner Mary Sheila Gall voting against).

The Commission then voted unanimously (1) that the regulation on lidocaine and dibucaine not be considered a final regulation until it is published in the **Federal Register**; (2) that the final regulation be published in the **Federal Register** on April 8, 1995, or as soon thereafter as practicable; and (3) to approve the most recent draft **Federal Register** notice that had been forwarded to the Commission.

Each Commissioner filed a separate statement concerning this matter. Copies of the Commissioners' statements can be obtained from the Commission's Office of the Secretary.

[2] Numbers in brackets indicate the number of a relevant document as listed in Appendix 1 to this notice. When a reference document that is cited in a document listed in Appendix 1 is referred to, both the number of the Appendix 1 document and the designation of the reference document as given in the Appendix 1 document are given, e.g., [1, Ref. A].

solutions, liquids, sprays, aerosols, and injectables. Tube packaging, used for creams, ointments, and some gels, protects its contents from contamination and moisture and enables the administration of a controlled volume of medication to smaller areas. Aerosol, spray, and squeeze bottles permit liquids to be applied to cover larger areas.

OTC liquid lidocaine preparations contain 1.5 to 2.5 percent lidocaine hydrochloride. The liquid preparations typically are packaged in squeeze or pump bottles or aerosol sprays and are labeled for external use only. Creams and ointments contain 0.5 to 2.5 percent lidocaine and typically are packaged in tubes. These products are recommended for children 2 years of age and older.

Approximately 12.1 million units of lidocaine-containing products were sold to consumer outlets in 1992. More than half (6.2 million) of these products were cream and ointment formulations available in tubes. In addition, the Commission's staff estimates that less than 0.4 million bottles of consumer-ready prescription viscous lidocaine were sold in 1992.

Prescription preparations intended for consumer use include a 2-percent viscous solution and at least two combination lidocaine creams. The prescription 2-percent lidocaine viscous liquids, in 100 ml bottles (3½ fluid oz), are available from 15 suppliers at estimated wholesale costs to pharmacies ranging from $2.28 to $4.40. One supplier also markets a 450 ml bottle of 2-percent viscous lidocaine that, according to a company spokesperson, is for pharmacy repackaging into smaller containers and dispensing as prescribed by physicians.

One combination cream, a lidocaine/hydrocortisone formulation, is marketed in a 1-oz tube; its estimated wholesale cost to pharmacies is $32.33. The other combination is a lidocaine/prilocaine-based cream, marketed in unit dose and 30-gm (slightly over 1 oz) tubes (cost unknown). The unit-dose, when used by the consumer, is intended to have its entire contents applied at home about 1 hour before a medical procedure that will be performed in a professional setting. The preparation is used also in professional settings.

The prescription 2-percent viscous solution of lidocaine is used for anesthesia of irritated or inflamed mucous membranes of the mouth and throat. Care must be taken following the oral use of viscous lidocaine because swallowing may be impaired. It is recommended that food not be ingested for 1 hour following oral use because of the potential for aspiration. For adults, it is recommended for mouth pain that one 15 ml tablespoon be swished around the mouth and spit out; for throat pain, the same amount can be gargled and either spit out or swallowed. The maximum recommended single adult dose is 4.5 milligrams/kilogram (mg/kg), not to exceed 300 mg. (A kilogram equals approximately 2.2 lb.) Although this form of lidocaine is applied to the mouth, or even swallowed, it is not considered to be a ''drug for human use that is in a dosage form intended for oral administration'' that already is required to be in CR packaging by 16 CFR 1700.14(a)(10). This is because its action is caused by topical application to the affected area and not by systemic action following ingestion.

For children under 3 years of age, it is recommended that ¼ teaspoonful be applied to the affected area with a cotton-tipped applicator. For children 3 years old and older, the dose is prescribed based on the weight and age of the child. The dose interval for children should be at least 3 hours, so as not to exceed 4 doses in a 12-hour period.

Previously, the Commission was aware of 7 marketers of trade name OTC pharmaceuticals containing lidocaine; 16 marketers are now known. Some marketers represent recently introduced preparations. Also, some preparations have been recently withdrawn from the market. Creams, ointments and some gel preparations are available in small (½- and/or 1-oz) tubes at estimated wholesale costs of $2.02 to $5.74. One supplier markets a preparation in a 35-gm tube (1.25 oz) at an estimated wholesale cost of $10.19. Liquid (and some gel) lidocaine preparations are available in aerosol, spray pump, and spray and squeeze bottle containers. Estimated wholesale costs for ¼–16 oz liquids and gels range from $1.74 to $5.46. One new marketer supplies a preparation for burn injuries in a foil packet containing ⅛ oz of gel. The preparation is currently promoted for use in the workplace rather than in the home; the company plans to introduce this product into the consumer market in the future.

Some lidocaine preparations, although dispensed through pharmacies, are intended for use in a professional setting such as a doctor's or dentist's office. According to pharmaceutical company spokespersons, these preparations include prescription lidocaine fluids such as 2 percent, 4 percent, and 5 percent liquid solutions; 2 percent jellies; 5 percent ointments; 4 percent viscous liquids; 10 percent oral sprays; 5 percent ophthalmologic solutions and drops; and prefilled syringes containing lidocaine solutions. Products that are not customarily consumed, used, or stored by individuals in or about the household are not required to comply with PPPA regulations.

Table 1 shows estimated 1992 total market sales of prescription and OTC consumer-use preparations containing lidocaine for each of five therapeutic categories in which lidocaine products are sold. Total sales of lidocaine preparations in 1992 are estimated at $36.6 million, about 12 percent of sales of all preparations in the five categories reviewed.

Based on IMS America data, the Commission's staff estimates 1992 unit sales of consumer-ready prescription 2-percent viscous lidocaine bottles at under 0.4 million bottles, a decrease of about 50 percent from the 1989 estimate of 0.8 million bottles. About 98 percent of prescription 2-percent viscous lidocaine preparations were marketed in consumer-ready 100 ml bottles in 1989 and in 1992. Many marketers and pharmacists are voluntarily providing CR packaging for these preparations.

Market shares of lidocaine-containing preparations (Table 2) show slight increases since 1989 in three categories: OTC Topical Anesthetics (up 1 percent); General Antiseptics (up 3 percent); and Burn Remedies (up 2 percent). The 9 percent increase in the market share of lidocaine preparations in the Topical Anti-infectives category is most likely due to new product introductions of combination antibiotic/anesthetic ointments and creams. The 1992 market share of prescription cortisone/lidocaine preparations remains unchanged from 1989.

TABLE 1.—ESTIMATED SALES: TOTAL MARKET [1] LIDOCAINE PREPARATIONS—TOPICAL DOSAGE FORMS

	1992	
	All preps Sales ($ millions)	Lidocaine preps Sales ($ millions)
Topical Anesthetics:		
(OTC)	97.7	2.0
(Prescription) [2]	3.3	3.3
General Antiseptics (OTC Only)	33.0	8.9
Burn Remedies (OTC Only)	25.1	9.2
Topical Anti-infectives (OTC Only)	135.4	13.1
Hydrocortisone Combinations (Prescription Only)	7.2	.1

TABLE 1.—ESTIMATED SALES: TOTAL MARKET[1] LIDOCAINE PREPARATIONS—TOPICAL DOSAGE FORMS—Continued

	1992	
	All preps Sales ($ millions)	Lidocaine preps Sales ($ millions)
Total	301.7	36.6

Source: IMS America, Ltd. and CPSC Directorate for Economic Analysis.

[1] Extrapolated from IMS America, Ltd. data to estimate total sales to drug stores, food stores, and mass merchandise outlets. Includes data provided by pharmaceutical company spokespersons.

[2] Includes only prescription 2-percent Viscous Lidocaine; all other prescription preparations in the category are for professional use.

TABLE 2.—ESTIMATED MARKET SHARES BY CATEGORY; LIDOCAINE PREPARATIONS 1992 AND 1989

	1992 (% Share)	1989 (% Share)
Topical Anesthetics (OTC)	2	1
General Antiseptics (OTC Only)	27	24
Burn Remedies (OTC Only)	37	35
Topical Anti-infectives (OTC Only)	10	1
Hydrocortisone Combinations (prescription Only)	2	2

Source: IMS America and CPSC Directorate for Economic Analysis.

Toxicity. [1] The toxicity of lidocaine has been demonstrated in animals and humans. Adverse effects have been observed in humans following both therapeutic usage and accidental overdosage. Lidocaine is readily absorbed through mucous membranes and abraded skin. The OTC preparations warn against using large quantities over raw or blistered areas or puncture wounds. The first-aid spray preparations warn against use near the mouth, eyes, ears, or other sensitive areas.

Absorption of lidocaine results in systemic side effects occurring most commonly in the cardiovascular and central nervous systems. Adverse effects range from minor effects, such as disorientation, dizziness, numbness, and drowsiness, to major effects, including convulsions, coma, and respiratory arrest. The blood level of lidocaine that is associated with toxic effects is a concentration of over 6 micrograms/milliliter (μg/ml). Major adverse effects occur with blood levels over 10 μg/ml.

Animal toxicity studies have been carried out with lidocaine using several different species and routes of exposure. Oral LD_{50} values for the rat and mouse are 317 mg/kg and 220 mg/kg, respectively. [1, Ref. Y] The median convulsive dose was calculated to be 75 percent of the lethal dose in one study. Id. The intravenous LD_{50} values were calculated to be 20–34 mg/kg in various mice studies and 25 mg/kg in the rat. Id. Although these animal data clearly demonstrate the high toxicity associated with lidocaine, the human experience data described below are more relevant for extrapolation to toxicity in children.

The staff is aware of nine deaths attributed to the accidental or intentional overdose of lidocaine:

The CPSC Death Certificate file contains a report of a three-year-old child who died in 1980 after the accidental ingestion of lidocaine. [4a] The causes of death were listed as cardiac arrhythmia and degenerative brain effects.

A second death certificate reports the 1981 death of a 2-year-old child after accidental overdose of a combination of two drugs, lidocaine and meperidine (a narcotic analgesic). Additional information is not available on this case. [4a]

The CPSC Reported Incident File contains the report of the death of an 11-month-old child, in 1984, from accidental ingestion of lidocaine. In this case, the child removed the CR closure from the product. [4b]

The FDA Adverse Reaction Reporting System reports an accidental death, in 1979, of a 13-month-old girl who ingested a Canadian viscous lidocaine product. The blood lidocaine concentration was 20 μg/ml. [4c]

A case reported in the literature describes the death, in 1986, of a 13-month-old boy. The boy had blood lidocaine levels of 19.5 μg/ml, remained unconscious, and was mechanically ventilated for 54 days. The child had suffered respiratory arrest at home prior to hospitalization. [1, Ref. Z]

A case investigated by CPSC staff involved the death in 1990 of a 14-month-old girl who ingested an unknown amount of 2-percent viscous lidocaine. Prior to the ingestion, the lidocaine had been applied to a diaper rash. The child's mother had placed the bottle in the crib while changing the child's diaper. The bottle had a CR closure, but it may not have been properly resecured. The mother did not believe the drug was hazardous, because she had been told by the pediatrician to rub lidocaine on the child's gums to ease teething pain. The toxicology report revealed high levels of lidocaine in the blood (12 μg/ml) and liver. [16, Ref. 1]

Another death in 1990 involved a 15-year-old girl who drank up to 480 ml of an OTC first-aid liquid containing 2.5 percent lidocaine. The cause of death was aspiration of gastric contents secondary to lidocaine intoxication. The serum lidocaine level was 18 μg/ml. [16, Ref. 2]

Two adult deaths due to intentional overdose of lidocaine are also reported in the literature. In these two cases, the blood lidocaine levels were 40 μg/ml and 53 μg/ml, respectively. [1, Ref. S]

The following cases reported in the literature describe non-fatal adverse effects observed in young children following therapeutic administration or accidental ingestion of lidocaine:

A 22-month-old child, weighing 10 kg, ingested 20 to 25 ml (approximately 50 mg/kg) of 2-percent viscous lidocaine. The child arrived at the hospital convulsing and not breathing. The child was successfully resuscitated, and the seizures were controlled. The child was discharged after 2 days with no long-term effects. [1, Ref. AA]

A 3½-year-old child was given one tablespoon of 2-percent viscous lidocaine (approximately 21 mg/kg) for a sore throat. The dose was repeated 4 hours later. The child developed seizures and had a lidocaine blood level of 10.6 μg/ml. The child was transferred to Pediatric Intensive Care in respiratory distress. The child was alert approximately 10 hours following the initial seizure and was discharged the following day. [1, Ref. BB]

A 15-month-old boy developed seizures following the prescribed use of lidocaine. The child's lidocaine blood level was 4.9 μg/ml. [1, Ref. BB]

A mother used a finger to apply 2-percent viscous lidocaine to an 11-month-old child's gums for teething pain, five or six times a day for a week. The child developed seizures and had a blood lidocaine level of 10 μg/ml. The child was treated in the intensive care unit and recovered after 4 days. [1, Ref. CC] Many articles in the medical literature warn physicians about the hazards of prescribing lidocaine for teething pain and related symptoms in young children.

A 5-month-old boy weighing 6.5 kg suffered seizures and required 48 hours of hospitalization after 1 day of treatment with oral viscous lidocaine. [24, p. 3 & n. 2] The 3.8 μg/ml serum lidocaine level, measured 4 hours after arrival at the emergency room, was in the high therapeutic range. The infant

required intubation to maintain respiration.

In another case, a 2-year-old drank from a bottle of viscous lidocaine, choked, and began convulsing within 10 to 15 seconds. [24, p. 3 & n. 3] Aspiration of lidocaine resulted in its rapid absorption. Serum lidocaine levels were 0.5 µg/ml 4 hours after the ingestion. The child remained hospitalized for 14 days with intubation and respiratory support.

FDA's Adverse Reaction Reporting System contains reports of two children (5 months old and 1 year old) who developed seizures after being administered viscous lidocaine. [5]

For the period 1978 through April 1990, the CPSC's Children and Poisoning (''CAP'') data base shows four ingestions of prescription viscous lidocaine and three ingestions of OTC lidocaine products by children under age 5. [6] All seven children were treated in National Electronic Injury Surveillance System (''NEISS'') hospital emergency rooms and released. Information on the amount of product ingested or adverse effects suffered by the children is not available.

Data collected by the FDA National Clearinghouse for Poison Control Centers from 1980 through 1984 [7] show 176 accidental ingestions of OTC lidocaine products, 18 of which exhibited toxic symptoms. These data also include 28 ingestions of prescription viscous lidocaine products, with 10 showing toxic symptoms. Details of the amount of product ingested or specific toxic symptoms are not available. This data base was discontinued after 1984.

For the years 1989 through 1991, the American Association of Poison Control Centers (''AAPCC'') reported 2,422 ingestions of lidocaine-containing products, 341 of which are known to have produced symptoms related to the exposure. Children under age 6 were involved in 1,898 of these ingestions. [23]

In addition to the cases noted above, several cases of accidental lidocaine poisoning in adults are reported in the literature. The reported cases demonstrate extreme variability in the development of toxicity of lidocaine, with children appearing to be more sensitive to the central nervous system side effects of the drug.

Level for Regulation. The maximum level of lidocaine that does not produce serious side effects in children is not known. The recommended maximum single total dose of lidocaine for children is 5.0 mg/kg, which is approximately 50 mg in a 10 kilogram (kg) child. However, as noted above, toxic effects were reported at therapeutic dose levels. The staff lacks sufficient information to establish that the reported cases involving toxic effects at therapeutic doses involved oral exposures (the route of administration most relevant to accidental ingestion) or that the proper therapeutic dose was not exceeded. It is possible, however, that a child who accidentally ingests a lidocaine preparation will already have received an intentional therapeutic dose of the preparation. In addition, the systemic toxicity of the drug is not the only hazard it presents; there is the risk of serious injury or illness caused by aspiration of substances that are swallowed while the mouth and throat are anesthetized by the drug. These considerations make it difficult to establish a package size that would not cause serious toxic effects if the contents are ingested by a small child.

Therefore, the Commissions staff recommended that the recommended maximum dose of lidocaine for a 10-kg child be reduced by a factor of 10 (referred to as an ''uncertainty factor'') in order to arrive at a level that would not cause serious injury or illness in young children. [1, 9, 24] After considering the comments on the proposal and other available information, the Commission accepted this recommendation. Therefore, products containing more than 5.0 mg of lidocaine in a single package will be subject to CR packaging standards.

C. Dibucaine

Product form, dosage and packaging. Dibucaine is used for temporary relief of painful sunburn, minor burns, scrapes, scratches, nonpoisonous insect bites, and external hemorrhoidal pain. OTC dibucaine preparations are marketed in 30-gm (slightly over 1 oz), 1-oz, 1.5-oz, and 2-oz tubes. It is used also in a few prescription preparations. It is also marketed in a 16-oz jar whose contents, according to the supplier, are used as the basis for a pharmacist-compounded and repackaged preparation. It is estimated that approximately 0.9 million tubes of dibucaine were sold to consumer outlets in 1992.

In 1994, the 13 suppliers of OTC dibucaine distributed 16 products, each in tubes of 25 grams (nearly 1 oz) or more. This reflects a decrease of over 50 percent in the estimated number of suppliers of generic OTC dibucaine since 1989, when there were 28 such suppliers. The 3 suppliers of prescription dibucaine preparations listed by Redbook in 1989 were not listed in 1992 or 1994.

Table 3 shows CPSC staff estimates of 1992 total market sales for OTC dibucaine preparations in the two categories in which dibucaine preparations are sold: OTC anti-hemorrhoidal and topical anesthetics. The market share of dibucaine-containing preparations reported in the topical anesthetics category remains at less than 1 percent, similar to the 1989 estimate. In the anti-hemorrhoidal category, dibucaine-containing preparations have an estimated 3 percent market share, down from 5 percent in 1989. Overall sales of dibucaine-containing preparations were an estimated $4.4 million.

TABLE 3.—ESTIMATED SALES: TOTAL MARKET;[1] DIBUCAINE PREPARATIONS—TOPICAL DOSAGE FORMS

	1992	
	All preps Sales ($ millions)	Dibucaine preps Sales ($ millions)
Topical Anesthetics (OTC)	97.7	.1
Anti-hemorrhoidal (OTC) ..	161.3	4.3

Source: IMS America, Ltd. and CPSC Directorate for Economic Analysis

[1] Extrapolated from IMS America, Ltd. data to estimate total sales to drug stores, food stores, and mass merchandise outlets. Includes data provided by a pharmaceutical company spokesperson.

The recommended dose for adults is to not exceed 1 ounce (equivalent to no more than 300 mg of dibucaine) in 24 hours. The recommended dose for a child, 2 years of age or older, is not to exceed ¼ ounce (equivalent to no more than 80 mg of dibucaine) in 24 hours.

Toxicity. Dibucaine is one of the most potent and toxic local anesthetics. Dibucaine produces serious systemic effects on both the central nervous system and the cardiovascular system. Adverse effects can include convulsions, depression of heart muscle contractility, and death. Dibucaine is readily absorbed through the mucous membranes and should not be used around the eyes or mouth. Systemic absorption may occur following the application of large amounts of dibucaine to large areas of abraded or damaged skin, or following rectal administration. The FDA disapproved the use of dibucaine in sore-throat and mouth medicines because of the possibility of systemic toxicity from dibucaine absorbed through the mucous membranes of the mouth and throat. [1, Ref. K]

The toxicity of dibucaine has been demonstrated in animals and humans. Animal studies indicate that dibucaine is lethal at three mg/kg in dogs, and one mg/kg in monkeys. [1, Ref. J] The toxic dose of dibucaine in humans is not known. However, the suggested maximum adult dose is 25 mg of dibucaine. [1, Refs. H, P]

The staff is aware of eight deaths of young children resulting from ingestion of dibucaine local anesthetics and of one death resulting from the rectal use of a dibucaine ointment:

During the 23-year period of 1951 through 1973, one manufacturer received reports of 11 cases of acute intoxications of young children from dibucaine topical preparations. [1, Refs. J, L] Ten of the cases involved accidental ingestion; one case involved the rectal use of dibucaine ointment in a 2-month-old infant. Four of the children who ingested the products died, as did the 2-month-old infant. Additional details of the incidents were not provided.

The CPSC Death Certificate File contains the report of a 2-year-old child who died in 1987 after accidentally ingesting a dibucaine cream used primarily for treating hemorrhoids. The child was found staggering by his mother, was lethargic, had seizures, and could not be resuscitated from respiratory arrest. The child had a dibucaine blood level of 1.3 µg/ml. [4d]

A second death certificate reports the death in 1988 of a 21-month-old child who accidentally ingested 22.5 grams of a dibucaine hemorrhoid ointment. Cardiorespiratory arrest and convulsions developed. The child could not be resuscitated after suffering cardiac arrest. [1, Ref. N; 4e]

CPSC has obtained a medical examiner's death report of an 18-month-old who died on July 10, 1994, after ingestion of a 1-percent dibucaine ointment. The victim may have ingested up to ½ oz of the product. The victim's father found the child suffering seizures in the family's kitchen. The victim was taken to a medical center and then transferred to a major children's hospital. The child was pronounced dead approximately 7 hours after the ingestion. [25]

Because of deaths reported from oral ingestion of dibucaine products, a warning was added to the labels of dibucaine products, stating:

''Should not be swallowed. Swallowing can be hazardous, particularly to children. In the event of accidental ingestion, consult a physician or poison control center immediately.''

For the period of 1978 through February 1990, the CPSC CAP data base shows two ingestions of dibucaine products by children under age 5. [6] Both children were treated in NEISS hospital emergency rooms and released. Information on the amount of product ingested or adverse effects suffered is not available.

Data from the FDA National Clearinghouse for Poison Control Centers from 1980 through 1984 show 113 ingestions of dibucaine products. Six of those individuals exhibited toxic symptoms. [7] This data base was discontinued after 1984.

The AAPCC National Data Collection System supplied to CPSC reports general data on the ingestion of topical local anesthetics, but does not contain specific information on the identity of the individual compounds involved. Lidocaine and dibucaine creams and ointments comprise only about 5 percent of the topical local anesthetics market. For the 5-year period 1984 through 1988, 10,330 cases of accidental ingestion of topical local anesthetics by children under age 5 were reported through that data system. [8] Of these cases, 883 exhibited minor-to-moderate symptoms and 10 were life-threatening or resulted in disability. The two cases that resulted in death were attributed to dibucaine, and are described above. Specific information on dibucaine ingestions was available for the years 1989 through 1991. The AAPCC received a total of 495 poison exposure cases involving dibucaine, 433 of which involved children under age 6. [23]

A review of the literature revealed one case in which a 12-month-old infant ingested a combination of three gm of boric acid and 300 mg of dibucaine. The child developed seizures, and also vomited due to the effects of the boric acid. The child was hospitalized and recovered fully after aggressive and intensive treatment. [1, Ref. M]

Level for Regulation. The high potency and toxicity of dibucaine are well known; however, an absolute level of safety for this drug is difficult to determine. Most cases of reported deaths contain little information about the concentration of the drug or the amount consumed. Ingestion of dibucaine, however, results in the same types of toxicity as does ingestion of lidocaine. The differences between the two compounds are in the potency and duration of action. Dibucaine is approximately 10 times more potent than lidocaine. Therefore, a correction factor of 10 was applied to the level for regulation derived for lidocaine to arrive at 0.5 mg as the level for regulation. [24]

This level of regulation for dibucaine is also supported by a case reported in the medical literature in which a 3-year-old child ingested 8 lozenges containing 1 mg of dibucaine each. The child died 8 hours later. The total dosage was approximately 0.5–0.8 mg/kg. [22] The author states that the child may have been sensitive to dibucaine.

D. Other Economic Considerations

[27] The total combined market for lidocaine and dibucaine (including OTC products and prescription viscous lidocaine) in 1992 totaled an estimated 13.4 million packages available to the consumer. This market declined 18 percent from the estimated 16.3 million packages reported in 1989. Decreases were reported in all formulations, most notably an estimated decline of 50 percent in the number of packages of consumer-ready viscous lidocaine.

Most lidocaine and dibucaine preparations are OTC products sold in packages that are not CR. The prescription creams/ointments in tubes are also in non-CR packaging.

Table 4 shows 1992 estimated total consumer-use units and market share by packaging type for the six categories in which IMS reports sales of lidocaine or dibucaine. Within the six categories, lidocaine or dibucaine preparations may not be marketed in specific package types. For example, there are no dibucaine preparations in spray packages. Additionally, there are no suppositories, pads, or wipes containing lidocaine or dibucaine. Units of prescription bottles used for 2-percent viscous lidocaine, discussed earlier, are excluded from this table. Lidocaine-containing preparations in all package forms amount to about 9 percent of topical anesthetic units. Nevertheless, lidocaine in spray packages dominates the market for spray topical anesthetic preparations (83 percent), and lidocaine in aerosol packages represents more than half (56 percent) of the topical anesthetics aerosol market. Lidocaine formulations packaged in tubes (creams, ointments, and gels) and bottles (liquids and gels) comprise 7 and 8 percent of units in their respective topical anesthetic package categories. Dibucaine-containing preparations, packaged only in tubes, represent about 1 percent of all tubes.

TABLE 4.—ESTIMATED 1992 UNITS;[1] CONSUMER-USE TOPICAL ANESTHETICS CONTAINING LIDOCAINE, DIBUCAINE, OTHER BY PACKAGE TYPE

Package type	1992	
	Units (millions)	Market share (percent)
Spray/Lidocaine	2.5	83
Spray/Dibucaine	.....	.....
Spray/Other	.5	17
Aerosol/Lidocaine	1.9	56
Aerosol/Dibucaine	.....	.....
Aerosol/Other	1.5	44
Tube/Lidocaine	6.2	7
Tube/Dibucaine	.9	1
Tube/Other	82.9	92
Bottle/Lidocaine	1.5	8
Bottle/Dibucaine	.....	.....
Bottle/Other	16.9	92
Suppository/Lidocaine	.....	.....
Suppository/Dibucaine	.....	.....
Suppository/Other	18.4	100
Pad or Wipe/Lidocaine	.....	.....
Pad or Wipe/Dibucaine	.....	.....
Pad or Wipe/Other	.8	100
Unknown/Other	2.3	.....
Total Lidocaine	12.1	9
Total Dibucaine	.9	1
Total Other	123.3	90

Source: IMS America, Ltd. and CPSC Directorate for Economic Analysis

[1] Extrapolated from IMS America, Ltd. data to estimate total sales to drug stores, food stores, and mass merchandise outlets for the six IMS categories in which lidocaine and dibucaine preparations are reported. Includes data provided by pharmaceutical company spokespersons.

TABLE 5.—ESTIMATED UNITS BY PACKAGE TYPE;[1] LIDOCAINE/DIBUCAINE PREPARATIONS 1992 AND 1989

Package type	1992 Units (millions)	1989 Units (millions)
Tubes	7.1	7.6
Prescription bottles	.4	.8
Aerosols	1.9	3.2
Spray/Bottles	4.0	4.7
Total	13.4	16.3

Source: IMS America, Ltd. and CPSC Directorate for Economic Analysis.

[1] Extrapolated from IMS America, Ltd. data to estimate total unit sales to drug stores, food stores, and mass merchandise outlets.

The following discussion of the economic impact of this rule is organized by the type of packaging. As noted above, lidocaine creams, ointments, gels, viscous solutions, and liquids are packaged in tubes, bottles and various spray containers. Dibucaine formulations are available only in creams and ointments and are packaged only in tubes.

Prescription viscous lidocaine packaged in prescription bottles. Most, if not all, suppliers of prescription 2-percent viscous lidocaine formulations dispensed in bottles are voluntarily using CR packaging in response to the Commission's 1986 request. CR packages for prescription bottles are readily available at low incremental cost. Therefore, the rule is not expected to have an adverse economic impact on businesses of any size that market viscous lidocaine in prescription bottles.

Lidocaine or dibucaine creams, ointments, and gels packaged in tubes. In 1992, an estimated 51 percent of lidocaine preparations (6.2 million units) and 100 percent of dibucaine preparations (0.9 million units) were packaged in tubes containing 2 oz or less. There are currently no commercially available CR packages to substitute for the small pharmaceutical tubes used to package creams, ointments, and some gels. Therefore, the PPPA requirement for topical anesthetics containing lidocaine or dibucaine will affect all marketers of the preparations packaged in tubes.

The Commission's staff identified nine marketers of OTC lidocaine preparations packaged in tubes. Four marketers that are considered ''small businesses'' account for about 11 percent of the lidocaine/tube preparation market. Dibucaine, available only in tubes, is marketed by 16 suppliers. Fifteen of these suppliers market generic and/or private-label products as part of extensive product lines. Specific sales data for the individual small marketers were not reported. However, a pharmaceutical company spokesperson reports the aggregate market share of small marketers is quite small. [27]

Under this rule, each marketer of lidocaine/dibucaine preparations packaged in tubes will have to consider one of three possible marketing options: development of acceptable CR packaging; reformulation to eliminate lidocaine or dibucaine as an ingredient; or withdrawal from the tube segment of the topical anesthetic market. Each marketer will probably choose the least costly alternative. These options are discussed below.

Reformulation: Marketers can reformulate to non-lidocaine/ dibucaine preparations and supply them in tube sizes comparable to those they are now using. Since many marketers have tube filling operations, this would enable the use of existing filling equipment. However, reformulation may result in the loss of a market ''niche'' held by a specific preparation. There also are potential costs associated with reformulation. For example, there may be research and development costs, costs to obtain FDA approval (if required), and additional marketing costs to regain market share. With this option, consumers would forego the use of the original preparations.

Develop CR packaging: Marketers can work with package manufacturers to develop CR multi-dose tubes compatible with specific lidocaine or dibucaine formulations. The Commission concludes that the development of CR packaging for these tubes is technically feasible, practicable and appropriate based on existing technology. [26] A pharmaceutical trade association contacted several major developers and suppliers of CR closures and provided the Commission with cost and time estimates to develop a CR tube package. The information supplied by the trade association stated that the development cost estimates ranged from $145,000 to $585,000 and that development would take 27–36 months. Additional time would be needed for stability testing of the preparation in the new package. Increased costs of up to $4.40 per tube are estimated if development is done on an individual company basis. Since marketers sell most lidocaine and dibucaine creams and ointments to pharmacies at prices ranging from less than $1.00 to about $6.00, the potential incremental cost of the tube might outweigh the cost of certain preparations provided by small marketers. [24]

Discontinue marketing: Some marketers may be unable to absorb the costs associated with the development of CR packaging for tubes while maintaining a competitive price for their products. The alternative option, reformulation, may lead to the loss of a market ''niche.'' As a result, some firms may decide to withdraw the lidocaine/ dibucaine tubes from the market. Based on 1992 estimated total sales of all lidocaine and dibucaine preparations ($41 million), with tubes accounting for about 53 percent of units sold, the potential loss of sales may be about $22 million if all such products were withdrawn. For small firms that have extensive product lines, abandoning lidocaine or dibucaine preparations may not be very disruptive, particularly if unit sales are low. For a few small companies with limited product lines or a niche preparation, withdrawal could result in disruption and financial loss. One small firm estimated lidocaine preparations represent 30 percent of sales, of which one-third is attributed to a preparation packaged in a tube. The other two small firms marketing

lidocaine in tubes would have less than 1 percent and less than 3 percent of their respective markets affected if these products are withdrawn. Thus lidocaine in tubes represents between less than 1 percent to 10 percent of these companies' total sales. As in the reformulation option, consumers would experience a loss of utility if manufacturers adopt this option. However, preparations with similar therapeutic qualities to any preparations withdrawn are available in the marketplace.

OTC Lidocaine liquids and gels packaged in bottles, pump sprays, metered sprays, and aerosol sprays. OTC lidocaine preparations in bottles and spray packages represented about 45 percent (5.9 million units) of lidocaine shipments in 1992. Ten marketers of these preparations have been identified. The preliminary economic assessment discussed the availability and incremental costs of CR packaging for these preparations. The lack of comments regarding the economic effects of the proposal for bottle and spray packages confirms the Commission's initial finding that costs to provide special packaging are comparatively low and likely not to have a substantial effect on marketers.

E. Comments on the Proposal

Ten comments were received on the proposal. The comments focused on several areas, including the level of drug for regulation, contentions that there is a lack of information to include all products with lidocaine and dibucaine, and the lack of a CR tube for creams and ointments. One commenter supported the rule. The Commission's responses to the comments are explained below.

Scope of the proposed regulation.

Comment: Several commenters indicated that the Commission had insufficient information to require CR packaging of all products containing lidocaine and dibucaine. The Nonprescription Drug Manufacturers Association (NDMA) stated that the Commission had not demonstrated that a significant number of children have been harmed by the accidental ingestion of OTC lidocaine and dibucaine. The NDMA contracted with Pegus Research to analyze poison exposures to OTC products containing topical anesthetics. The study examined poisoning incidents associated with OTC products containing lidocaine, dibucaine, and benzocaine.

Response: The staff's review of the toxicity of lidocaine and dibucaine was included in the February 27, 1992, briefing package for the proposed rule and updated in a supplemental package dated May 27, 1992. The documents described nine deaths attributed to the accidental or intentional overdose of lidocaine and several medical case reports of adverse effects following therapeutic administration or accidental ingestion of lidocaine. Six of these deaths were children under 5 years of age. The majority of the cases where the formulation is known involved 2-percent viscous lidocaine (a prescription drug). One death followed an intentional ingestion by a 15-year-old of an OTC product containing 2.5 percent lidocaine. The staff toxicity review described the deaths of six children (two known to be under 5 years of age) following the ingestion of dibucaine. An additional death of an 18-month-old girl following the ingestion of dibucaine ointment was reported recently.

While the data do not indicate whether any of the accidental deaths of children associated with lidocaine involved OTC formulations, these products contain amounts of lidocaine similar to the prescription viscous formulation. Young children are being exposed to OTC topical anesthetic products containing lidocaine or dibucaine. This is verified by the NDMA-sponsored study. The CPSC staff's analysis indicates that the proportion of children under 6 exposed to lidocaine or dibucaine is significantly larger than the proportion of children in this age group exposed to other substances.

The Commission concurs with the conclusion of the NDMA-sponsored analysis that the lidocaine and dibucaine poisonings generally do not have severe outcomes. However, four deaths from these compounds were documented from 1987 to the present, attesting to the toxicity of these substances.

Cream and ointment products are included in the rule because details from the three most recent deaths following ingestion of dibucaine (1987, 1988, 1994) specified that dibucaine was in a cream or ointment formulation. These deaths demonstrate the toxicity of dibucaine and the potential for toxicity from cream and ointment formulations in general.

Comment: A manufacturer of a male genital desensitizing agent containing lidocaine indicated that the Commission had not considered this product class and therefore it should not be covered in the rule.

Response: At the time of the proposal, the staff was unaware of the FDA's monograph for male genital desensitizing agents. Because the ingestion cases do not specify the formulation of the OTC lidocaine products, the staff cannot determine if any poisoning exposures are attributed to this class of products. However, the rule should not exempt these products, since the potential for injury and death from these lidocaine-containing products is equivalent to other OTC lidocaine spray products. The amount of lidocaine in one metered spray of this product exceeds the 5 mg regulated amount. Tests of a similar metered-spray package have shown that 48 of the 50 children in the test for child resistance actuated the spray and that, on average, each of the 48 actuated the spray over 90 times each during the 10-minute test. [30]

Inhalation and aspiration of aerosol and spray products can result in absorption from the lungs. The local anesthetic drugs are also readily absorbed through mucous membranes of the mouth and throat, therefore, an ''ingestion'' does not have to occur to result in toxicity. Aerosol and spray product formulations are included in the proposed rule because a child can access a potentially harmful dose. There is a documented case of a child spraying himself with another topical anesthetic (benzocaine 20 percent). The child experienced cardiac arrest resulting in death.

Comment: One commenter indicated that the rule should be clarified to exempt formulations of lidocaine intended for administration by injection. The commenter contended that lidocaine for injection purposes does not fit the definition of a household substance as described in the PPPA regulations.

Response: The Commission disagrees with the commenter's contention that the PPPA does not apply to injectable prescription pharmaceutical products. The definition of ''household substance'' in section 2(2) of the PPPA includes drugs and other hazardous substances that are ''customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household.'' 15 U.S.C. 1471(2). However, the PPPA does not extend to products used exclusively in hospitals, in nursing homes, or by medical professionals, because such items are not customarily consumed, used, or stored by individuals in or about the household. If the injectable lidocaine preparations truly are for professional use only and are not available to the consumer for use or storage at home, it is not necessary to separately state an exemption of these products.

However, if lidocaine injectable formulations were customarily available

for home consumer use (as is the case with insulin), the products would not be exempted. Injectable lidocaine is a liquid formulation that could be accessed by children if available in the home. The commenter provided no rationale for excluding these products in that case.

The staff is aware of other lidocaine-containing prescription products that may be used exclusively by physicians, dentists, and in hospital settings. A company supplied the staff with information about the usage of these products during a meeting on October 15, 1992. The products include creams, jellies, and liquids. The liquids are available in prefilled syringes, ampules, sprays, and bottles. As discussed above, if these products are for professional use only and are not obtained by consumers for use or storage at home, the requirements of the PPPA do not apply.

Regulated levels of lidocaine and dibucaine. Comment: Several comments were received regarding the proposed amount (level) of the two drug products that should be regulated. One commenter questioned the use of a 10-fold uncertainty factor for lidocaine. Another commenter questioned the use of an additional 10-fold factor for dibucaine.

Response: The level for regulation of lidocaine- and dibucaine-containing products is based on the maximum recommended single therapeutic dose of lidocaine (5 mg/kg or 50 mg for a 10 kg child). A 10-fold uncertainty factor was used to arrive at the 5 mg level of lidocaine.

It is true that a 10-fold uncertainty factor applied to a recommended therapeutic dose provides a more stringent level for regulation than that normally used by CPSC staff. Applying the uncertainty factor to the therapeutic dose is justified for lidocaine and dibucaine, however, for the following reasons: (1) Toxicity can occur at therapeutic doses of lidocaine and dibucaine; (2) children are particularly susceptible to the toxic effects of repeated therapeutic doses of these drugs; (3) since these drugs are used on children as well as adults, an accidental exposure could occur following a previous therapeutic dose of the drugs; (4) the metabolites of lidocaine and dibucaine are potentially toxic, especially to young children; and (5) risks of aspirating food or liquids are associated with oral exposure to these drugs, even at nonlethal and therapeutic doses. These reasons support the level chosen for regulating lidocaine.

The level for regulation of dibucaine was derived from the level for lidocaine, based on the relative difference in potency of the two drugs. Dibucaine is approximately 10 times more potent than lidocaine; therefore, the staff applied an additional 10-fold factor to the 5 mg level for lidocaine to arrive at a 0.5 mg level for dibucaine. While the commenter questioned the use of the additional 10-fold correction factor for dibucaine, the commenter agreed that dibucaine is approximately 10 times more potent than lidocaine.

The commenter suggested an alternative level derived from ingestion cases reported to the company. The commenter considers the cases to be confidential information, so they are not discussed here in detail. However, in addition to the cases discussed by the commenter, there was a death of a 3-year-old child following the ingestion of 8 lozenges, containing 1 mg of dibucaine each, that was reported in the medical literature in 1955. The child died 8 hours later from respiratory failure. The total dosage was approximately 0.5–0.8 mg/kg. The authors speculated that the child may have been sensitive to this drug product; however, dibucaine is very potent and readily absorbed from mucous membranes. The FDA later disapproved the use of dibucaine as an active ingredient in oral health-care products. The level of regulation being adopted for dibucaine (0.5 mg) is supported by this reported literature case. The Commission believes that these are appropriate levels for regulating lidocaine and dibucaine.

Comment: One commenter indicated that a 10-fold correction factor was not necessary for metered spray products because a child cannot spray enough to obtain a toxic blood level. The commenter indicated that the male genital desensitizing agent packages ''already are child resistant in that the drug product is dispensed in a metered spray.'' The commenter estimates that only ⅓ of each spray would be absorbed by a child. The commenter states that any risk of aspiration is unsupported.

Response: Metered sprays are tested for child-resistance as described in 16 CFR 1700.20 for unit packaging. The commenter provided no test results describing how many sprays a child can access during the test period. It should be noted that each spray of the commenter's product contains 7.68 mg of lidocaine per spray, an amount greater than the recommended level for regulation. This product contains 150 sprays per container. The FDA monograph for these preparations restricts the dosage to 10 mg of lidocaine per spray. Thus each spray of a male genital desensitizing agent can contain two times the proposed level for regulation for lidocaine. The commenter did not supply data to support its estimate of the access and absorption of the product.

The commenter also contended that the 10-fold uncertainty factor for lidocaine was established because of the Commission's concern for the aspiration hazard for sprays. This is not the case. Aspiration following oral usage of local anesthetics is documented in the medical literature and in CPSC injury records and is not limited to aerosol products. [24, Refs. 3, 7]

Comment: Commenters stated that the 5-mg level for lidocaine and the 0.5 mg level for dibucaine were below the therapeutic concentrations recommended by the FDA for cream and ointment preparations.

Response: The level for regulation does not affect or restrict the concentration of the product. The Commission's rule simply requires that products containing more than the regulated level must have CR packaging. The comment about the regulated levels being below the therapeutic concentrations can be interpreted as a complaint that the level is too restrictive and that all lidocaine- and dibucaine-containing products would require CR packaging. However, this is not the case, since the PPPA allows a manufacturer or packager to package an OTC product in one size of non-CR packaging if the manufacturer also supplies the products in CR packages and the non-CR package is labeled properly. The amount of product in the noncomplying package is not restricted.

Effectiveness of Requiring CR Packaging. Comment: One commenter supported the rule but stated that CR packaging would have prevented only a few of the deaths. This commenter stressed the need for enhanced educational activity. In addition, several commenters indicated that the viscous lidocaine responsible for two of the deaths was already in CR packaging. Other commenters indicated that the rule would have a limited effect, since no deaths have occurred in the past several years.

Response: Several of the deaths described in the toxicity review were accidental or intentional overdose cases. The purpose of discussing these cases is to illustrate the toxicity of the products. The results of the study of ingestion cases indicate that children are accessing products containing lidocaine and dibucaine. There were 676 ingestions of lidocaine-containing products and 110 ingestions of dibucaine-containing products by children under 5 years of age reported to poison control centers in 1992. [29]

While most of these children did not experience major effects, each of the ingestions had the potential to result in serious injury or death. For example, with dibucaine, a company reported four deaths of children who accidently ingested dibucaine products from 1951 to 1973. Two more deaths were reported in 1987 and 1988, more than 10 years after the last reported death. The death reported in 1994 demonstrates that the risk of injury from dibucaine continues to exist. CR packaging requirements may prevent future deaths from products containing these ingredients.

No information is available as to whether the ''CR'' packaging, used voluntarily by several companies, actually meets the criteria of the PPPA regulations. A requirement for CR packaging of these products, instead of voluntary usage, would permit CPSC to enforce the PPPA requirements for these products.

CR packaging has saved many lives, but CR packaging is not child proof. The Commission agrees that education is an important part of poison prevention. The Commission acts as the secretariat for the Poison Prevention Week Council, which promotes the poison prevention message.

Development of CR Tubes. Closures that can be put on the small tubes that are in current production to make them child resistant are not currently commercially available. The following discussion addresses some general comments related to packaging for the cream and ointment products.

Comment: One manufacturer supplied limited test results of a 1-inch diameter plastic squeeze tube with a European 18-mm ASTM type IA closure. The company reported that the package was closed at 7 inch-torque-pounds (ITP). Twenty children were tested, and eleven children were able to open the package during the test period. None of the children used teeth to open the package. The commenter contended that these test data show that CR tubes are not technically feasible.

Response: The staff indicated in the proposed rule that special packaging for tubes could be achieved by using commercially available 22-mm closure bottle threads on a suitable laminated plastic tube. This would allow the use of a ''senior friendly'' ASTM type IA continuous threaded closure to be used to obtain child-resistance. The staff is unaware of any data from protocol tests conducted on a tube with the 22-mm ASTM type IA closure.

The child-resistance function of the European closure used by this commenter is unknown. This closure has never been tested by the Commission on any package. It is difficult to know whether the failures in the test were associated with the closure itself or a problem with the combination of the closure and tube. The package tested had a small diameter closure, and 7 ITP is a very low closing force. Both of these factors make the package more accessible to children. The larger closure size (22 mm) proposed by the CPSC's staff is harder for children to remove and easier to put on at higher forces. These data do not change the Commission's view that a plastic tube can be made CR using a 22-mm ASTM type IA closure and existing technology. See also Section E.2, below.

Comment: Commenters indicated that unit packaging is not appropriate for products containing lidocaine and dibucaine because the FDA does not define a dose for lidocaine- and dibucaine-containing creams and ointments. Commenters indicated that people use varying amounts of these products depending on the indication for use and the potential for partial use exists. In addition, the NDMA stated that one of their members attempted to package in a foil pouch and could not achieve stability of the product.

Response: The Commission is aware of the lack of a defined dose for lidocaine and dibucaine. The Commission agrees that nonreclosable packaging for many of the creams and ointments may not be possible due to this variation in the definition of single use and the potential for residual product in the package. It is difficult to package a unit amount for these products that will not result in potential harm to children if it is not completely used. A package cannot be marketed containing less than the regulated amount, because this level is below the therapeutic level required by the FDA.

The technical finding of appropriateness includes shelf life and stability. Neither the NDMA, its member companies, nor other commenters supplied data to document the lack of stability in pouches. The staff is aware of a lidocaine-containing product packaged in foil pouches. This product is currently used in industrial settings, although the company advertises the potential for home use. The Commission recognizes that not all formulations are equivalent; different ingredients have different stability properties. However, the Commission believes that suitable pouch materials can be found for any lidocaine- or dibucaine-containing product. Because of the problem of hazardous residual amounts, however, the amount packaged would have to be extremely small. Therefore, pouches or other unit-dose packages may not be a practical way to market these products to comply with the regulation.

Comment: Bottles and jars are unsuitable for cream and ointment formulations of hemorrhoidal relief use products, and anesthetic first aid products due to preservation and contamination issues.

Response: Other creams, such as cosmetic cold creams, are packaged in jars. However, the usage of these products differs substantially from the usages of lidocaine- or dibucaine-containing products. Since lidocaine- and dibucaine-containing products are used in the anal area (hemorrhoidal preparations) or on open wounds (first aid preparations), the Commission agrees that contamination is possible if individuals reenter the container for more product without washing their hands thoroughly. This limits the appropriateness of jars and bottles for these products.

Comment: Plastic or laminate tubes are not a viable alternative. One commenter reported that it cannot achieve stability of the lidocaine product in plastic or laminate tubes.

Response: Metal tubes currently are used for packaging many lidocaine-containing products and all the dibucaine-containing products. The proposed rule indicated that manufacturers may have to change from a metal tube to a plastic tube to achieve child-resistance. No commenter supplied data to support the claim that stability cannot be attained in plastic or laminate tubes. One manufacturer currently markets a lidocaine-based cream product in a plastic tube. Although the different vehicles in different formulations have different stability properties, development testing will determine which plastics or laminates are compatible with any particular formulation.

Comment: Tubes cannot be made CR because children will bite through the tube, thereby gaining access to the tube's contents. The NDMA cited the opinion of Dr. Alexander Perritt, president of Perritt Laboratories, a CR package testing laboratory.

Response: One NDMA member supplied limited child test data to the Commission staff. The company tested a plastic tube with a CR closure that allegedly meets the different European child-resistance standards on other types of packaging. While many of the 20 children tested in these tests opened the tube package, none did so with their teeth. There is no reason to conclude that tubes cannot be made sufficiently strong to withstand the teeth of children under age 5.

Additional information on the technical feasibility of plastic tubes is in Section E.2 of this notice.

E. Statutory Considerations

1. Hazard to children. Pursuant to section 3(a) of the PPPA, 15 U.S.C. 1472(a), the Commission finds that because of the toxic nature of lidocaine and dibucaine preparations, described above, and the accessibility of such preparations to children in the home, the degree and nature of the hazard to children in the availability of such substances, by reason of their packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting these substances.

2. Technical feasibility, practicability, and appropriateness. [26] In issuing a standard for special packaging under the PPPA, the Commission is required by section 3(a)(2) of the PPPA, 15 U.S.C. 1472(a)(2), to find that the special packaging is ''technically feasible, practicable, and appropriate.'' Technical feasibility exists when technology exists or readily can be developed and implemented by the effective date to produce packaging conforming to the standards. Practicability means that special packaging complying with the standards can utilize modern mass production and assembly line techniques. Appropriateness exists when packaging complying with the standards will adequately protect the integrity of the substance and not interfere with the intended storage or use.

A. Technical feasibility. Lidocaine and dibucaine prescription and OTC products are presently packaged in tubes, spray containers, aerosols, and prescription containers. Most of the current packaging appears to be non-CR. The manufacturers of most viscous lidocaine-based non-oral prescription drugs have voluntarily packaged these drugs in consumer-ready CR prescription containers, even though they are not now required to do so under the PPPA regulations. [2, Ref. 3] For those manufacturers using non-CR packaging, various types and designs of non-tube CR packaging can be obtained.

CR packaging for OTC and prescription tubes can be accomplished by using commercially available bottle threads on plastic tubes. [2, Ref. 4] This would allow the use of readily available CR continuous-threaded closures on the tube. The Commission is aware of tubes now on the market that use bottle threads that could be outfitted with existing push-and-turn continuous-threaded CR closures. However, the Commission does not know that such CR tubes are available in all the sizes currently used or lidocaine and dibucaine products. Therefore, it may be necessary for the manufacturers of these products to develop and test such packaging and incorporate it into their production lines. For those manufacturers using metal tubes, a change to a plastic tube, with appropriate stability testing, may be necessary.[3]

The Commission's determination that plastic tubes for these products are technically feasible has been confirmed by additional information. One cap manufacturer has notified the Commission that it has two cap designs that should be suitable. [37] One of these is currently commercially available in stock sizes as small as 20 mm, including the 22 mm size relied on in the proposal. This cap is child-resistant under the Commission's current regulations and meets the proposed senior-friendly requirements that may be adopted in the future (see Section I of this notice). The other cap is a squeeze-and-turn model that currently is not available in sizes below 28 mm. However, the manufacturer indicated that a development program for smaller sizes would require 3 months to produce prototypes, with full commercial availability in an additional 6 months.

Another manufacturer submitted information showing steps leading to a child-resistant plastic tube with appropriate stability characteristics that could be distributed commercially within a 52-week period. [35]

Technical feasibility for lidocaine prescription drug products and OTC spray containers that are presently in non-CR packaging is demonstrated by: (1) Many manufacturers are voluntarily using CR packaging (ASTM type IA closures on bottles) for prescription 2-percent viscous lidocaine consumer-ready preparations. (2) CR packaging for OTC products that are dispensed by spraying is also commercially available. Similar CR packaging designs have passed the proposed protocols for ''senior friendly'' packaging. (See section I below.)

CR packaging for aerosol and mechanical pump packaging is technically feasible and commercially available. The staff has information that this type of packaging can be made senior friendly. Additional time to develop suitable packaging may be necessary for some products containing lidocaine, due to the small size of the package. For example, male genital desensitizing agents containing lidocaine are available in metered spray packaging containing less than ½ oz. An overcap can be made for this product that would require the use of a tool to remove. It is unknown whether this feature would be senior friendly on this small package. If not, it may be necessary to use an alternative type of package, such as a larger diameter aerosol with a CR and senior-friendly overcap. Manufacturers of these products and other products available in small mechanical pumps or aerosols may need more than 1 year to develop senior-friendly CR packaging for these small packages. However, as noted above, larger diameter packages can be used, and such packages could be available within 1 year.

There are numerous continuous-threaded special packaging designs that can replace the non-CR continuous-threaded closures presently being used with viscous lidocaine prescription medication and OTC spray packaging.

CR packaging for aerosols also can be obtained, and a number of commercially available designs could be used. Therefore, the Commission concludes that there are numerous package designs that meet the requirements of 16 CFR 1700.15(b) that are suitable for use with the forms of these products.

b. Practicability. Companies that are presently using CR packaging for viscous prescription drug products containing 2-percent lidocaine have implemented assembly line and mass production techniques in their manufacturing processes. This shows that it is practicable to package 2-percent viscous lidocaine-containing products in special packaging. No major problems from the manufacturing standpoint are anticipated in the change from non-CR to CR packaging, except for the multiple-dose tube-type packaging,

[3] There are other potential designs for making metal tubes CR. [26] Those designs are not being relied upon to make the technical feasibility finding in this proceeding, however, because they were not discussed in the proposal and, therefore, not made available for public comment.

One alternative CR package design that can be adapted to the existing metal tubes involves modifying a hinged snap cap. A continuous-threaded cap with a hinged snap cap can be permanently attached to the threads of the tube. The snap cap can be modified by providing a slot to allow opening of the package with a tool. This design, if developed, should be both CR and senior friendly. Moreover, it can be adapted to existing metal tubes and be mass produced without degrading the integrity of the product.

In addition, two prototype closures were made for metal tubes in the past. While these were never developed commercially, the prototypes illustrate different approaches that can be used to achieve CR tube packaging.

Furthermore, a company has indicated that metal tubes can be provided with threads that can accommodate existing continuous-threaded closures known to be child resistant on other package types. [31, 33]

which may require the use of a contract packager.

The manufacturers of non-tube CR packaging do not anticipate any problems with supplying CR closures and containers. The major suppliers of CR packaging and materials indicate that they can supply more than the 6.2 million non-tube units estimated to be needed for lidocaine and dibucaine products.

In most cases, manufacturers can incorporate CR packaging into their existing packaging lines. If there were any problems in modifying or obtaining new equipment, i.e., capping, etc., a contract packager could be used in the interim to package lidocaine- and dibucaine-containing products. Many existing designs suitable for use with the products that are the subject of the regulation are currently being used in the packaging of other products, or can be readily developed. Special packaging for this product is therefore practicable in that it is adaptable to modern mass production and assembly line techniques. The Commission anticipates no major supply or procurement problems for the packagers of these products or the manufacturers of CR closure and capping equipment.

c. Appropriateness. Information available to the staff indicates that the CR packaging of lidocaine- and dibucaine-containing products is appropriate. Some companies are presently voluntarily using special packaging for their viscous prescription drug products containing 2-percent lidocaine. Other companies can utilize existing CR packaging designs and materials that are not detrimental to the integrity of the substance and do not interfere with its storage or use. Product shelf-life and integrity would not be expected to change, as it is anticipated that the same packaging materials could be used in contact with the product.

In the case of the multiple-dose CR tube packaging, however, it may be necessary, for example, to change from a metal tube to a plastic tube in order to provide a suitable mating surface for a CR cap. A major product manufacturer contacted by the Commission's staff indicated that it could find an appropriate multilayer plastic tube to replace the metal tube, but that the suitability of the new tube would have to be confirmed by protocol and product stability testing.

The Commission concludes, therefore, that special packaging is appropriate because it is available in forms that are not detrimental to the integrity of the substance and that do not interfere with its storage or use.

Accordingly, the Commission finds that special packaging is technically feasible, practicable, and appropriate.

3. Reasonableness. In establishing a special packaging standard, section 3(b) of the PPPA requires the Commission to consider the available data concerning whether the standard is reasonable. 15 U.S.C. 1472(b). However, the Commission is not required to make a positive finding that the standard is reasonable. S. Rep. No. 91–845, 91st Cong., 2d Sess. 10 (1970).

After considering the available data, the Commission concludes that there are no data that warrant a conclusion that the proposed rule is not reasonable.

4. Other considerations. Section 3(b) of the PPPA also requires the Commission, in establishing a special packaging standard, to consider:

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

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

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

The Commission has considered these items in making the various determinations in this notice.

F. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such regulation is final,[4] 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 Commission concludes that production of CR packaging can be fully implemented within a year from the publication of this rule. Therefore, the final rule will become effective April 10, 1996, as to all products subject to the rule that are packaged on or after that date.

This 1-year effective date may not allow adequate time to modify or replace all multiple-dose tubes, aerosols, and mechanical pumps if unusual difficulties are encountered, if the initial design intended to be CR is found to be unsuitable, or if data on the stability of the package contents need to be approved by the FDA. Where necessary, affected parties using any type of package can apply to the Commission for a temporary exemption for the minimum period required to market their products in CR packaging. Applications for such exemptions should describe the efforts since the issuance of the final rule to implement complying package designs, explain why such efforts were diligent yet unsuccessful, and explain why additional efforts within a limited period should result in a complying package.

G. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act (Pub. L. 96–354, 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. The purpose of the Regulatory Flexibility Act, as stated in section 2(b) (5 U.S.C. 602 note), is to require agencies, consistent with their objectives, to fit the requirements of regulations to the scale of the businesses, organizations, and governmental jurisdictions subject to the regulations. Section 605 of the Act 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 initial certification indicated that the incremental costs for CR packaging for lidocaine preparations in aerosols and squeeze and spray bottles were comparatively low and likely to have a minimal effect on small businesses. Since the proposal, the staff has not received any additional information regarding adverse impacts on small business from comments on the proposed rule or from any other source. Therefore, the Commission concludes that the action to require CR packaging for topical anesthetics containing lidocaine packaged in aerosols, squeeze, and spray bottles will not have a significant economic effect on a substantial number of small entities.

The initial certification indicated also that packaging industry spokespersons were unaware of any appropriate types of CR packages for the small pharmaceutical tubes now used to package lidocaine and dibucaine creams and ointments (and some gels). The analysis concluded that if costs associated with the use of alternate packaging were prohibitive to small manufacturers, they may drop the product from their lines. Since the proposal, the staff has received additional information regarding

[4] The Commission voted on September 28, 1994, to issue this rule, and, at that time, the Commission directed that the rule would become final on its date of publication in the **Federal Register**. The Commission also directed that the date of publication would be April 8, 1995, or as soon thereafter as practicable.

adverse impacts of the proposed rule on small businesses.

Industry representatives have confirmed that there are no known CR closures commercially available for the small pharmaceutical tubes currently used to package creams, ointments, and some gels. Although CR unit-dose sachets are available, specific chemical formulations used in various preparations are reported to be incompatible with the materials used for the sachets. Since there is no alternative packaging currently commercially available, some small businesses advise that a PPPA requirement for creams and ointments containing lidocaine or dibucaine will result in the withdrawal of their products from the market. For a few small companies, particularly those with limited product lines or a niche preparation, withdrawal could result in disruption and financial loss, as discussed in Section D of this notice.

The Commission concludes that the action to require CR packaging for topical anesthetics containing lidocaine or dibucaine cream and ointment formulations may have an adverse effect on a few small businesses, but the number of businesses subject to such effects is not likely to be substantial.

For the reasons given above, the Commission certifies that the rule will not have a significant economic impact on a substantial number of small entities.

H. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission assessed the possible environmental effects associated with the proposed PPPA packaging requirements for topical drug preparations containing lidocaine or dibucaine and presented its findings in the Preliminary Economic Assessment (Revised April 1992). Re-assessment of the possible environmental effects confirms the original determination that the rule will have no significant effects on the environment. There is little likelihood that CR unit dose tubes or sachets will replace the currently used multi-dose tubes. But even if unit dose packaging was available, the amount of additional packaging used would be relatively insignificant. Since there appears to be no alternative packaging for preparations packaged in tubes, the proposal will affect only preparations packaged in bottles and various forms of spray containers. Manufacturers of affected products will have time to use up existing closure inventories and will not need to dispose of them in bulk. The rule will not significantly increase the number of CR packages in use and, in any event, the manufacture, use, and potential disposal of the CR packages present the same potential environmental effects as do the currently used packages.

Therefore, because this rule has no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

I. Possible Changes to the PPPA Test Protocol

For the purpose of determining whether a package is CR, the current regulations provide that a package must be capable of resisting opening by 85 percent of a panel of 200 children after a 5-minute test and by 80 percent of the panel after an additional 5-minute test. In order to determine that the package can be used by adults, the package must also be able to be opened and, if appropriate, properly closed within 5 minutes by 90 percent of a panel of 100 persons of ages from 18 to 45 years.

On October 5, 1990, the Commission proposed to amend its requirements under the PPPA. 55 FR 40856. In its proposal, the Commission concluded that, if CR packages were easier to use, more people would purchase and properly use CR packaging. Accordingly, the Commission proposed to substitute a panel of 100 older adults, of ages from 60 to 75 years for the panel of 18- to 45-year-olds. The Commission also solicited comment on allowing a 5-minute familiarization period in the adult test, during which the subject must open the package, before the 1-minute test. 56 FR 9181 (March 5, 1991). Other amendments, intended to simplify the current child test procedures, add a procedure for determining whether the package was adequately resecured by the adults, and to ensure that the tests produced more consistent results, were also proposed.

The Commission received a number of comments on the proposed rule, and contracted for additional testing to obtain information to address the comments on the proposed 5-minute/1-minute test. On March 21, 1994, the Commission published a **Federal Register** notice outlining the new information obtained, describing possible changes to the proposed test procedure, and requesting comment on these matters. 59 Fed. Reg. 13264. The possible changes to the test procedure included:

1. Dividing the 60–75-year-olds into 3 age groups and distributing the participants in the groups to reduce variability.

2. Modifying the sequential testing scheme for older adults to provide more certainty about passing or failing ''borderline'' packages. This involves testing sequential panels of 100 seniors, up to 400 subjects, until a statistically valid determination is made.

3. Adopting the 5-minute/1-minute older adult test on which comment was sought previously.

The additional data also resulted in other minor changes to the proposal and provided information that the Commission can use to address other comments that did not warrant any changes.

The Commission may vote later this year on whether to issue these revisions to the PPPA protocol. Manufacturers of lidocaine- and dibucaine-containing products are urged to consider changing to CR packaging that not only meets the current PPPA requirements but will meet the new procedures that may be adopted. This would eliminate any need to change packaging twice in a relatively short period of time.

List of Subjects in 16 CFR Part 1700

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

J. Conclusion

For the reasons given above, the Commission amends 16 CFR 1700 as follows:

PART 1700—[AMENDED]

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

Authority: Pub. L. 91–601, secs. 1–9, 84 Stat. 1670–74, 15 U.S.C. 1471–76. Secs. 1700.1 and 1700.14 also issued under Pub. L. 92–573, sec. 30(a), 88 Stat. 1231, 15 U.S.C. 2079(a).

2. Section 1700.14 is amended by adding new paragraphs (a)(23) and (a)(24) and the introductory text of paragraph (a) is republished 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 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:

* * * * *

(23) Lidocaine. Products containing more than 5.0 mg of lidocaine in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of § 1700.15(a) and (b).

(24) Dibucaine. Products containing more than 0.5 mg of dibucaine in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of § 1700.15(a) and (b).

Dated: April 3, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

Appendix 1—List of References

(This Appendix will not be printed in the Code of Federal Regulations.)

1. Memorandum from CPSC's Directorate for Health Sciences, dated June 21, 1990 (toxicity).
2. Memorandum from CPSC's Directorate for Health Sciences, dated July 24, 1989 (technical feasibility, practicability, and appropriateness).
3. Memorandum from CPSC's Directorate for Economic Analysis, dated December 10, 1991 (a. economic information; b. regulatory flexibility analysis; and c. environmental assessment).
4. Death and injury data:
a. CPSC Death Certificate File, 1981, lidocaine.
b. CPSC Injury or Potential Injury Incident File, 1984, lidocaine.
c. FDA Drugs and Biologics Adverse Reaction Reporting System Data Base, 1979, lidocaine.
d. CPSC Death Certificate File, 1987, dibucaine.
e. CPSC Death Certificate File, 1988, dibucaine.
5. FDA Drugs and Biologics Adverse Reaction Reporting System Data Base.
6. CPSC National Electronic Injury Surveillance System Data Base—1978 through April 1990.
7. National Clearinghouse for Poison Control Centers Data Base 1980–1984.
8. AAPCC National Data Collection System 1984–1988.
9. Briefing package, OS #3309, ''Draft Proposed Rules—Special Packaging Standards For Topical Anesthetics,'' February 27, 1992.
10. Briefing package, ''Supplemental Information—Special Packaging Standards For Topical Anesthetics,'' May 27, 1992.
11. Log of Meeting with Ciba Consumer Pharmaceuticals, April 8, 1992.
12. Memorandum from CPSC's Directorate for Economic Analysis, ''Market Sketch: Topical Preparations Containing Lidocaine and Dibucaine,'' Oct. 2, 1990 (revised April 23, 1992).
13. Memorandum from CPSC's Directorate for Economic Analysis, ''Supplemental Information on Lidocaine and Dibucaine,'' April 23, 1992.
14. Memorandum from CPSC's Directorate for Health Sciences, ''The Amount of Lidocaine and Dibucaine in Marketed Products,'' April 27, 1992.
15. Memorandum from CPSC's Directorate for Economic Analysis, ''Amended Economic Data: Proposal to Require Child-Resistant Packaging for Topical Preparations Containing Lidocaine or Dibucaine,'' dated April 27, 1992 (with revised preliminary economic assessment).
16. Memorandum from CPSC's Directorate for Health Sciences, ''Additional Human Experience Data for Lidocaine and Dibucaine,'' April 27, 1992.
17. Memorandum from CPSC's Directorate for Health Sciences, ''Supplemental Information on Lidocaine and Dibucaine,'' May 28, 1992.
18. Log of Meeting with NDMA Lidocaine/Dibucaine Task Force, October 15, 1992.
19. Comments on proposed rule (10). On file in the Office of the Secretary.
20. Log of meeting with Ciba Consumer Pharmaceuticals, January 11, 1994.
21. Log of Meeting with NDMA Lidocaine/Dibucaine Task Force, May 25, 1994.
22. McClenahan, W., Fatal Poisoning with Dibucaine Hydrochloride (Nuporal) Lozenges, Journal of American Medical Association, 158(7), 565, 1955.
23. Memorandum from Terry L. Kissinger, EPHA, ''Response to Comments and analysis of Available Data Regarding Child-resistant Packaging for Topical Anesthetics Containing Lidocaine or Dibucaine,'' April 29, 1994.
24. Memorandum from Susan C. Aitken, Ph.D., HSPS, ''Health Sciences Staff Responses to Comments on Proposed Packaging Standards for Lidocaine and Dibucaine,'' July 19, 1994.
25. Memorandum from Terry L. Kissinger, EPHA, ''Recent Death Involving Ingestion of a Dibucaine-Containing Product,'' July 27, 1994.
26. Memorandum from Charles J. Wilbur, HSPS, ''PPPA Final Rule Lidocaine and Dibucaine Technical Feasibility, Practicability, and Appropriateness,'' July, 1994.
27. Memorandum from Marcia P. Robins, ECSS, ''Final Economic Assessments: Proposal to Require Child-resistant Packaging for Topical Anesthetics Containing Lidocaine or Dibucaine,'' June 15, 1994, (and telephone conversation 10/1/93).
28. Letter from Vincent De Stefano (Ciba Consumer Pharmaceuticals) to Ann Brown, June 10, 1994.
29. Poison Control Centers Toxic Exposure Surveillance System, 1992.
30. Wilbur, Charles J., Laboratory Report, form 221, Non-CR Finger Mechanical Pump Spray with Overcap, 2 fl. oz., S–400–0802, CPSC, August 2, 1994 (Confidential).
31. Memorandum to file, Mike Gidding, CEAL, ''Memorandum of visit to Teledyne Corporation,'' August 4, 1994.
32. Letter from Andrew S. Krulwich and Julie Jacobs, counsel to Combe, Inc., to Eric A. Rubel, General Counsel, in support of exemption for OTC topical lidocaine preparations, September 8, 1994.
33. Memorandum from Suzanne Barone, HS, to the Commission, ''Supplemental Information on Lidocaine and Dibucaine,'' September 9, 1994.
34. Vote sheet from the Office of the General Counsel to the Commission, with revised **Federal Register** notice, September 9, 1994.
35. Log of meeting and attached material submitted by a manufacturer—FOR OFFICIAL USE ONLY.
36. Letter from John B. Dubeck, Keller and Heckman, on behalf of Pound International, Inc., September 12, 1994.
37. Letter from Jeffrey C. Minnette, Sunbeam Plastics, September 16, 1994.
38. Memorandum from Marcia Robins, ECSS, to Suzanne Barone, Ph.D., Project Manager, HS, ''Lidocaine/Dibucaine'' (about share of revenue for lidocaine in tubes for three small companies), September 19, 1994.
39. Letter from Andrew S. Krulwich and Julie Jacobs, Wiley, Rein & Fielding, on behalf of Combe, Inc., September 20, 1994.
40. Tape recordings of Commission briefing on September 21, 1994 (portion containing discussion of confidential data is for official use only).
41. Letter from John Dubeck, Keller and Heckman, representing Pound International, September 26, 1994 (non-confidential version).
42. Additional data from AAPCC, September 27, 1994.
43. Revised draft **Federal Register** notice, September 27, 1994.
44. Tape recording of Commission meeting on September 28, 1994.
45. Separate statements of the Commissioners.

[FR Doc. 95–8628 Filed 4–7–95; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 290

Defense Contract Audit Agency (DCAA) Freedom of Information Act Program

AGENCY: Office of the Secretary of Defense, DoD.

ACTION: Final rule.

SUMMARY: This administrative amendment is published to inform potential FOIA requestors of the geographical coverage of Wyoming from the Western region to the Central region as part of its reorganization. This part also authorizes the ''DCAA Label 4'' (For official use only coversheet).

EFFECTIVE DATE: (April 10, 1950).

FOR FURTHER INFORMATION CONTACT:

Mr. Dave Henshall, Attn: CMR, Defense Contract Audit Agency, Cameron Station, Alexandria, VA 22304–6168, telephone 703–274-4400.

List of Subjects in 32 CFR Part 290

Freedom of information.

Accordingly, 32 CFR Part 290 is amended as follows: