other comments, the Commission decided to exclude from the proposed rule products that do not present the risk of aspiration because of the way the product is dispensed. For example, aerosol products (i.e., pressurized spray containers) that expel the product in a mist do not pose the risk of aspiration. The Commission also excluded products packaged in mechanical pumps and trigger sprayers that expel product in a mist, provided that the spray mechanism is either permanently attached to the bottle or has a child-resistant attachment. This makes the misted pump or trigger sprayer package equivalent to an aerosol can. If the aerosol can, mechanical pump, or trigger sprayer expels product in a stream (either solely or as an option), the spray mechanism and the means for affixing it to the reservoir container must be child-resistant. Aerosols and permanently affixed pumps or triggers may use a child-resistant overcap in lieu of a child-resistant actuating mechanism. Also, aerosol products that form a stream only when an extension tube is inserted into the nozzle would be excluded from the packaging requirements if, without the tube, the product is expelled as a mist.

The FHSA regulation partially exempts small packages, minor hazards, and special circumstances from the FHSA's labeling requirements. 16 CFR 1500.83(a). Writing markers and ballpoint pens are exempt from full cautionary labeling requirements relating to toxicity if they meet certain

specifications listed in the regulations. These products are also excluded from the proposed child-resistant packaging requirements due to the difficulty a child would have obtaining a toxic amount of fluid from these types of products. For the same reason, products that are packaged so their contents are not free-flowing, such as some battery terminal cleaners, paint markers, and make-up removal pads, are excluded from the proposed child-resistant packaging requirements.

The following section describes some of the products that may be subject to a child-resistant packaging standard if the proposed rule is ultimately issued.

C. Products That May Be Subject to the Proposed Rule

The proposed standard includes all household products as defined in the PPPA, unless exempted, that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F. This would impact many different classes of products that currently do not require child-resistant packaging. However, not all of the products within each category would require child-resistant packaging under the proposed rule, because many of those products do not meet the specified composition and viscosity criteria.

The staff identified several different automotive products that would require child-resistant packaging under the proposed rule. These products include carburetor cleaners, fuel injection cleaners, and some gasoline

additives. Many of these products are intended for single use, and some are already in child-resistant packaging. Automotive lubricants, including motor oil and spray lubricants, for the most part will not be included in a proposed rule because motor oils have high viscosities and aerosols that expel the product as a mist are excluded from the proposed rule.

Other household chemicals subject to the proposed rule include spot removers and water repellents. Several of the spot removers that the staff identified were already in child-resistant packaging. However, the water repellents, especially those made for shoe care, are not. Cleaning products, including some floor and metal cleaners, would also be impacted by the proposed rule. Some miscellaneous sports-related products, including gun cleaners and archery arrow feather water repellents, contain hydrocarbons but were not in child-resistant packaging. Most writing instruments, including all markers and pens, are exempt from the proposed rule because they do not expel free-flowing hydrocarbons.

The current PPPA regulation requires child-resistant packaging of solvents for paint and other surface coatings, but child-resistant packaging of paint and varnishes themselves is not currently required. Most paints would not be included in the proposed rule because they contain insufficient hydrocarbons or are too viscous. However, some

sealers, non-water-based varnishes, and stains may be covered. As discussed above, aerosol spray paints are not included in the proposed rule.

There are several categories of cosmetics that would be included in the proposed rule. In general, creams and lotions are not subject to the rule because they are either too viscous or are emulsions. Most baby oils, excluding lotions and gels, would be included in the proposal. The inclusion of other cosmetic products depends on their viscosities. Because of their composition and viscosities, some bath and suntan oils would be subject to the proposed rule, while others would not. Make-up removers and nail/cuticle conditioners may or may not require child-resistant packaging depending on hydrocarbon content, viscosity, and product form. Wipes and saturated pads are exempt.

These are the major product groups that have been identified. There may be other individual products that would require child-resistant packaging that have not been identified either by the staff or the comments on the ANPR.

The following section addresses the comments on the ANPR and further discusses the rationale for the scope of this rule.

D. The Commission's Response to Comments on the ANPR

The ANPR was sent to 221 trade associations and businesses believed to be involved with petroleum-

distillate-containing products. Thirty individuals and groups submitted comments. Four commenters (comments numbered CP97-2-3,-11,-12,-18) supported the rule. Most of the other comments focused on which products should or should not be subject to such a rule.

1. The scope of the rule.

(a) Aerosols. Comment: Should a child-resistant packaging standard for low-viscosity petroleum distillates include aerosol products?

Response: There is insufficient evidence to demonstrate that there is a serious aspiration hazard from self-pressurized aerosols or spray mists that contain petroleum distillates. The commenters cited the results of animal studies conducted in the 1960's. The staff is not aware of new animal or human experience data that would change the conclusions that misted aerosols sprayed into the mouth do not pool in the mouth to result in aspiration. Accordingly, hydrocarbon-containing products in pressurized containers, that are expelled as a mist, are exempt from the proposed child-resistant packaging requirements.

Under the FHSA, special labeling related to toxicity is required for products containing 10 percent or more by weight of toluene, xylene, and petroleum distillates that may be aspirated into the lungs and result in chemical pneumonitis and death. For aerosol products, this special labeling under 16 CFR 1500.14(b)(3) related to the ingestion

of hydrocarbon-containing products is required only when the contents are expelled as a stream. The industry requested that all hydrocarbon-containing aerosols be exempted from the child-resistant packaging requirements. However, a large volume delivered directly into the mouth could result in aspiration. Therefore, self-pressurized packages of hydrocarbon-containing products that can be dispensed in a coherent stream would be subject to the proposed child-resistant packaging requirements. Aerosol products that form a stream only when an extension tube is inserted into the nozzle would be excluded from the packaging requirements if, without the tube, the product is expelled as a mist. The CPSC laboratory staff determined that these products can be expelled through the extension tube at a rate of 1-2 ml/sec (Cobb, March 8, 1999). However, it is unlikely that a 2- or 3-year-old child would obtain a sufficient amount of fluid via this route to cause an aspiration hazard.

(b) Viscosity. Issue: What is the appropriate viscosity for requiring child-resistant packaging of products that contain hydrocarbons?

Response: After reviewing the submitted data and comments pertaining to viscosity, the Commission determined that the viscosity level where child-resistant packaging is not needed to protect children should remain at or above 100 SUS at 100°F. This is the viscosity below which the FHSA

regulations require precautionary labeling for ingestion of petroleum distillate-containing products and the PPPA regulations require child-resistant packaging of three product categories (furniture polish, paint solvents, and kindling and illuminating products).

Commenters and the medical literature agree that lower viscosities are associated with a greater risk of aspiration; however, there is no agreement about defining a "safe" upper level for viscosity. One published review article suggests that products with viscosities of 60 SUS or greater have low aspiration potential (Litovitz and Greene, 1988). Another recent review article recommends that only products with viscosities of less than 73.4 SUS require labels warning about the hazard of aspiration (Craan, 1996).

A draft revision to the Canadian Consumer Chemicals and Containers Regulations (CCCR) adopts 73.4 SUS and below for child-resistant packaging and cautionary labeling requirements. The current Canadian labeling and packaging requirements (CP97-2-23) use 70 SUS as the upper level. There are concerns about this level because aspirations and resulting serious injury or death from pneumonitis and lipoid pneumonia have been documented with mineral oil-based products such as baby oil (Reyes De La Rocha et al, 1985, Perrot et al, 1992, IDI 97030HCC9033). These products have viscosities in the 60-75 SUS range.

Another comment asserted that the appropriate upper level based on the animal studies by Gerarde in the 1960's was 81 SUS (Klein, July 16, 1998, Gerarde, 1963). However, this level is too low, since it is at or close to the viscosity associated with aspiration of products that resulted in deaths and serious injuries. Therefore, the proposal includes products with viscosity levels less than 100 SUS at 100°F within the child-resistant packaging standard.

This would expand the current child-resistant packaging requirements from those limited to furniture polish, kindling and illuminating fluids, and paint solvents to include other product categories with similar ingredients and viscosities.

(c) Hydrocarbons other than petroleum distillates. Issue. Should a child-resistant packaging requirement include products that contain hydrocarbons other than petroleum distillates?

Response: Comments for and against including hydrocarbons other than petroleum distillates were received. Some commenters wanted to limit the rule to petroleum distillates. Other commenters suggested that compounds with the same risk of aspiration should be regulated regardless of their source. The Commission's decision falls between these two suggestions. The proposed rule includes products with solvents containing only hydrogen and carbon, commonly

known as "hydrocarbons." The term "petroleum distillate" is archaic and refers to mixtures of hydrocarbons that are distilled from petroleum. There has been confusion about "petroleum distillates," especially regarding the aromatic hydrocarbons benzene, xylene, and toluene. The aromatics are components of some of the distillation fractions. However, the aromatics are not universally considered to be petroleum distillates because the toxicity of aromatics differs from the aliphatic chemicals. The Canadian standards currently do not include the aromatic hydrocarbons in their definition of petroleum distillates for cautionary labeling and child-resistant packaging (CP97-2-23).

In order for the proposed rule to be definite and comprehensive, the Commission proposes to not use the term "petroleum distillate" to define the scope of the rule. Instead the rule applies to those chemicals that contain only hydrogen and carbon. This will minimize confusion by making it clear that the aromatic hydrocarbons are intended to be included in a child-resistant packaging requirement. However, this does not change the FHSA's specific labeling requirements for the aromatic hydrocarbons. The Canadians have taken a similar approach. A draft revision to the Canadian standard eliminates the term "petroleum distillate" and lists chemical structures and classes to clarify what is included in the regulations.

Using the term hydrocarbon clarifies that the rulemaking will not be limited to petroleum-derived chemicals. It also eliminates one commenter's concern about confusion over whether the chemical limonene includes several different compounds. The recommended rule does not name individual compounds. Whether a product would require child-resistant packaging would depend on the total amount of hydrocarbon (by weight) and the product's viscosity.

The draft standard in Canada extends the requirements for labeling and packaging of aspiration hazards to include certain alcohols and ketones. The CPSC did not expand this rulemaking to include non-hydrocarbon chemicals, such as terpene alcohols, ketones, or alcohols, because of the diverse chemistry, toxicity, and uses of these chemicals. These non-hydrocarbon chemical classes should be evaluated separately for the need for child-resistant packaging.

(2) Restricted flow.

Issue: Should restricted flow be an additional requirement for certain products?

Response: Restricted flow is defined in 16 CFR 1700.15(d) as ".... the flow of liquid is so restricted that not more than 2 milliliters of the contents can be obtained when the inverted, opened container is shaken or squeezed once or when the container is otherwise activated once." Restricted flow is required in addition to child-resistant packaging for liquid furniture polish because many

ingestions occurred while the product was in use and the top was already off. 16 CFR 1700.14(a)(2).

Restricted flow alone is not adequate to protect children, however. It does not prevent the child from directly accessing the product if the package is not child-resistant. Although restricted flow limits the amount of product a child can obtain each time the child attempts to ingest the product from the container, it does not limit the number of attempts the child may make.

None of the commenters identified a product class as needing restricted flow in addition to child-resistant packaging. Several commenters mentioned that restricted flow would impede the use of products where greater volumes are necessary for use. These commenters did not identify specific products.

A commenter requested that restricted flow be an alternative to child-resistant packaging for cosmetic products such as baby, body, and bath oils. The commenter stated that older adults might have difficulty opening the child-resistant packaging with hands wet from the bath or shower. The commenter stated that many of these products already had restricted flow.

The CPSC staff examined some cosmetic products with restricted orifices. None of these products met the PPPA's regulatory definition of restricted flow. The PPPA test procedures use adults aged 50 to 70 to determine

adult-use-effectiveness for most packaging. This has led to the development of packaging systems that are easier for all adults to use properly (including resecuring the cap).

Furthermore, the rationale for restricted flow with furniture polish is that children would have access to the bottle during its use, in addition to when it was in storage. Therefore, the restricted-flow requirement is in addition to, not in lieu of, child-resistant packaging.

The Commission has not identified any specific product or product category where restricted flow would add additional protection to children. Therefore, the Commission is not requiring restricted flow for additional product categories. The requirement for restricted flow of liquid furniture polish currently in the PPPA regulations will remain.

(3) Injury data.

Comment: Several commenters (CP97-2-6, -15, -19-21) stated that the number of incidents and deaths were low and that child-resistant packaging was not justified.

Response: The CPSC believes that child-resistant packaging regulations should not be based solely on the number of incidents known to have occurred in the past. Before issuing a regulation under the PPPA, the Commission must find that "the degree or nature of the hazard to children in the availability of hydrocarbons, 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." 15 U.S.C. 1472(a)(1).

The ANPR presented ingestion data from various sources, including the CPSC's National Electronic Injury Surveillance System ("NEISS") and the Toxic Exposure Surveillance System ("TESS") maintained by the American Association of Poison Control Centers ("AAPCC"). The staff collected additional information on the NEISS cases where possible. The data collection was limited to product categories that may contain petroleum distillates and that are not currently required to be in child-resistant packaging. From these data, it can be shown that children do gain access to the categories of products that include some products that contain hydrocarbons.

The potential for aspiration and serious injury from these chemicals is well documented. Each time a child gains access to one of these products that is not in child-resistant packaging, there is the potential for ingestion, aspiration, pneumonitis, and death. Therefore, the Commission is proposing to require child-resistant packaging to protect children from accessing these products.

(4) Packaging.

(a) Exempt aerosols. Comment: One commenter (CP97-2-20 and 20a) stated that there are no currently available child-resistant/senior-friendly overcaps for aerosols. The

commenter requested that the rule be clarified to say that aerosols are exempt from the senior-friendly requirements.

Response: The PPPA regulations exempt from the senior-friendly portion of the PPPA's requirements products that must be in aerosol form and products that require metal containers with reclosable metal closures. 16 CFR 1700.15(b)(2)(ii)(A). It is unnecessary to repeat this exemption specifically in a rule for hydrocarbon-containing products. However, the staff is aware of several child-resistant overcap designs that meet the senior-friendly requirements. The Commission will consider revisiting this issue in the future, but it is outside the scope of this rulemaking.

(b) Exempt single-use products with heat seals.

Comment: Several commenters (CP97-2-20a and 7) requested that single use products with heat seals be exempted from the requirements.

Response: Any regulated product that is intended and likely to be fully used in a single application must meet the child-resistance and adult-use-effectiveness specifications for only the first opening, since a toxic amount of the product will not remain after the product is opened and used. The manufacturer may use any packaging option that meets the PPPA requirements for the first opening. The CPSC has no data from tests of packages with thermal foil seals.

(5) Miscellaneous.

(a) Education campaign. Comment: The CSMA and several of its members (CP97-2-20, -15) requested that CPSC work with them and others on an education campaign to encourage consumers to read product labels and follow the directions and cautions. They request this because several of the incidents occurred while the product was not in its original container and, therefore, child-resistant packaging would not have prevented the incidents.

Response: The Commission agrees that education has value when used to communicate a safety message. Consumers need to be reminded to use child-resistant packaging properly. However, education does not replace the need for child-resistant packaging. Child-resistant packaging prevents ingestions and saves lives directly by creating a barrier between the child and the substance.

(b) Parental responsibility. Comment: One commenter (CP97-2-4) indicated that the issue was one of parental responsibility and that regulation was unnecessary.

Response: The issue of parental responsibility and child poisoning is not new. The Congressional Committee on Commerce dealt with this issue while drafting the Poison Prevention Packaging Act of 1970. The Committee report states, " . . . parental negligence is not the primary cause of poisonings. There are too many potentially hazardous products in the modern home to hope that all of them can be

kept out of the reach of children." Child-resistant packaging creates a barrier between the child and the hazardous product when adult vigilance is insufficient. Therefore, the Commission proposes a rule to protect from ingesting products having the same potential aspiration hazard as other products that currently are required to have child-resistant packaging.

(c) Labeling. Comment: Comments (CP97-2-6, -25) were received stating that the labeling required under the FHSA was adequate to protect against the hazard and that child-resistant packaging was therefore unnecessary.

Response: Labels make important information available to the consumer; however, poisoning data demonstrate the inadequacy of labeling alone as an injury prevention strategy. The PPPA itself recognizes that FHSA labeling is not necessarily adequate to protect children by giving the Commission the ability to require child-resistant packaging for products that are toxic and thus already have to bear precautionary labeling including "Keep out of the reach of children." Human experience shows that it is unrealistic to expect labels to provide the same degree of protection as child-resistant packaging.

(d) Garage storage. Comment: A comment (CP97-2-1) stated that automotive products should not be included because they are stored in the garage and children do not have access to them.

(e) Response: The NEISS and TESS data included in the ANPR demonstrate that children do gain access to automotive products. These products should be in child-resistant packaging if they contain hydrocarbons and can be aspirated. Several companies voluntarily package their hydrocarbon-containing automotive products in child-resistant packaging.

(f) Graffiti and "huffing." Comment: One commenter (CP97-2-25) stated that child-resistant packaging of aerosol paints would not prevent vandalism or inhalant abuse (huffing).

Response: The Commission agrees with the commenter. The purpose of this rulemaking is to prevent children under 5 years of age from ingesting products that result in serious injury. To the extent that graffiti and huffing are done by older children, this recommended rule would have little, if any, effect on these behaviors. To the extent the comment argues that aerosols should not be subject to the rule, most (those that expel the substance as a mist) are not.

(g) Increased risk of injury to children. Comment: The Cosmetics, Toiletries, and Fragrance Association (CP97-2-28) commented that requiring child-resistant packaging on baby oil could result in an increase in babies falling from changing tables or an increase in drowning incidents in bath tubs because parents would have to use both hands to open the package.

Response: According to the CTFA, about 70 percent of baby oil is used on adults and not babies. The comment assumes that adults who use baby oil on children now use only one hand to open and squirt out the product. The CTFA provided no evidence to support this. Containers for other baby products, including tubes or jars, often require two hands to open or use. The labeling on baby powder, for example, instructs parents to sprinkle the powder into their hands and then rub it on the baby. The comment also assumes that two hands are required to open all child-resistant packaging. In fact, however, there are child-resistant designs that can be opened with one hand. Further, parents can open the baby oil container ahead of time. The Commission finds it highly unlikely that baby oil in child-resistant packaging would increase the number of falls and drowning incidents.

E. Injury Data

The following section updates the ingestion data from household chemical products. The injury data reviewed at the time the ANPR was issued did not include cosmetic products. The CPSC staff has now reviewed ingestions of cosmetics product categories, including nail products, sunscreen and suntan preparations, bath oil and creams, lotions, and make-up, and the results are outlined below, along with a separate discussion of baby oil ingestion data.

1. Household chemicals.

The CPSC maintains the NEISS database of product-related injuries that were treated in hospital emergency rooms. The NEISS data are derived from a statistical sample of hospital emergency rooms in the United States. However, many ingestion exposures are handled by Poison Control Centers and are not treated in emergency rooms. The TESS database, which includes calls to poison control centers, is not a statistical sample, and the numbers of incidents cannot be used to make national estimates. The number of exposures reported in TESS represents a large percentage of the total calls to poison centers in a given year. However, the total annual number of ingestion incidents is likely to be greater than the actual number of cases reported in TESS.

The CPSC staff examined the NEISS data for ingestions by children under 5 years of age for the years 1995 through 1997. The product categories examined include workshop chemicals, adhesives, lubricants, metal polishes, automotive chemicals, paints, varnishes, and shellacs, spot removers, and automotive waxes, polishes, and cleaners. There were an estimated 6,800 ± 1,800 pediatric ingestions of these products seen in emergency rooms during the 3-year period.

In addition, the CPSC purchases TESS data for children under 5 years of age from the AAPCC each year. The data purchased include reported exposure calls. Informational calls are not purchased. The data do not include trade

names. They are coded for broad product categories in a single code. The CPSC staff examined unintentional ingestion incidents from categories that contain products that may require child-resistant packaging under the regulation. These include carpet, upholstery, leather, or vinyl cleaners; automotive hydrocarbons; hydrocarbon spot removers; lubricants; other hydrocarbons; unknown hydrocarbons; other or unknown rust removers; floor wax, polish, or sealers; toluene or xylene adhesives; toluene or xylene; stains; and varnish and lacquers.

There were 44,781 ingestions of these products recorded in TESS for the years 1995-1997 (12,592, 16,433, and 15,756, respectively). Of these ingestions, 612 cases were also coded as aspirations. According to TESS guidelines, aspiration cases are automatically coded as ingestions in the TESS system. Of the aspiration cases, 122 resulted in "moderate" medical outcomes and 4 in "major" outcomes. No deaths from these product categories were reported during this period. A number of children had specific respiratory effects that were the direct result of the aspiration of the product. These include 31 cases of pneumonitis, 5 cases of respiratory depression, and 1 case of pulmonary edema.

Not all products in these categories contain hydrocarbons or have a viscosity of less than 100 SUS at 100°F. For example, many of the adhesives and lubricants may have viscosities higher than 100 SUS. However, the data

demonstrate that children do access the types of household chemical products that can contain hazardous levels of hydrocarbons. If these products contain hydrocarbons and have viscosities less than 100 SUS at 100°F, children are at risk of aspiration and pneumonia. If the products are not hazardous hydrocarbon-containing products, the proposed rule does not affect them.

(2) Cosmetics.

NEISS does not have specific codes for cosmetic products. Therefore, NEISS data are not included in the review of cosmetics ingestions. CPSC staff examined TESS data for the years 1995-1997 for 4 general cosmetic categories known to have products that contain hydrocarbons. These include miscellaneous nail products, sunscreen and suntan preparations, bubble bath and bath oil, and creams, lotions, and make-up.

There were 74,042 ingestions of these products recorded in TESS for the years 1995-1997 (21,850, 25,514, and 26,678, respectively). Of these ingestions, 114 cases were coded as aspirations. Of the aspiration cases, 5 resulted in "moderate" medical outcomes, 2 in "major" outcomes, and 1 in a death (from baby oil). A number of children had specific respiratory effects that were the direct result of the aspiration of the product. These include 2 cases of pneumonitis, 2 cases of respiratory depression, and 1 case of respiratory arrest.

As stated previously, not all of the products in the categories contain hydrocarbons. For example, bath oil may contain hydrocarbons, but bubble bath is usually an aqueous detergent solution that would not be covered by the rule. In addition, not all of the hydrocarbon-containing products in each category would require child-resistant packaging because they have viscosities of 100 SUS or more at 100°F. Creams and lotions that are emulsions would also not be included. For example, the staff collected a convenience sample of 5 different tanning products labeled as containing mineral oil and measured the viscosities and percentages by weight of hydrocarbons in these products. Of the five tanning products collected, one was an emulsion (lotion), two were tanning oils with viscosities in the 240 SUS range, and two were tanning oils with viscosities in the 65 SUS range. Only the latter two products would require child-resistant packaging under the proposed rule. This analysis cannot be extrapolated to identify the percentage of products in any category that may fall within the scope of the recommended rule. The example illustrates that there can be a range of viscosities in cosmetic products in the same category.

The cosmetic trade association argues that the aspiration hazard does not exist for cosmetic products. However, some companies warn about the possibility of serious injury on their labels, using the following: "For

external use only. Keep out of children's reach to avoid drinking and accidental inhalation, which can cause serious injury. Should breathing problems occur, consult a doctor immediately." The FDA does not require this warning. The FDCA (21 CFR 740.1(a)) requires that "the label of a cosmetic product bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product."

The TESS database documents aspirations from cosmetic products. In addition, the reported cases of serious injuries and a death from baby oil, regardless of the circumstances and whether child-resistant packaging would have prevented them, reinforce and support the potential hazard of these products. The viscosities of these products fall in the range where aspiration may be a hazard. The poisoning data indicate that children are accessing household chemicals and cosmetics that contain hydrocarbons. The potential for serious injury exists.

(3) Baby oil.

The Commission was specifically interested in incidents involving baby oil. A literature review documented one case of serious injury following aspiration of baby oil (Reyes de la Rocha, et al., 1985). The CTFA's comment documented a similar case that resulted in permanent impairment of a child. The limited details that the CTFA supplied did not directly correlate with the published case. The two cases

may not be the same. Moreover, there was a death of a child following ingestion of baby oil documented by the AAPCC (Litovitz et al., 1997). The CPSC staff investigated the circumstances of the death (IDI 97030HCC9033); however, limited information was obtained. The child died 23 days after the ingestion. There was speculation that between 10 and 14 ounces of baby oil may have been ingested, although it was reported that the child was covered with baby oil. According to the AAPCC report a part of the cap was found in the child's stomach. The CTFA questioned the circumstances of this death. Nevertheless, the reported decrease in oxygen saturation and lung infiltration are consistent with aspiration pneumonitis.

The CPSC purchased data on exposures to baby oil by children under 5 years of age that AAPCC had compiled for the years 1996 and 1997. Over 2,500 incidents were reported during the 2-year period. Most of these cases involved ingestion. Most of the cases were managed at home. Several children exhibited symptoms and were admitted to the hospital. The CTFA also purchased these data and commented. It concluded that the data demonstrate the safety of baby oil.

The Commission is concerned about products such as baby oil that use lightweight mineral oil and have viscosities in the 60-99 SUS range. The authors of one report of a case involving baby oil conclude that "baby oil aspiration can be

one of the causes of acute respiratory distress in children" (Reyes de la Rocha, 1985). They advocate that the latent danger of baby oil needs to be publicized since it appears that baby oil is not recognized as a cause of diffuse pneumonia and respiratory distress. This was demonstrated in a recent case documented in NEISS (981026HEP9021). An infant was accidentally given baby oil. According to the mother, she was told by the poison control center and the pediatrician that the child would have diarrhea. However, 3 days later the child was admitted to the hospital with pneumonia. While child-resistant packaging would not have prevented this ingestion, the case illustrates the potential dangers of the lightweight-mineral-oil-based products with viscosities under 100 SUS.

F. Technical Feasibility, Practicability, and Appropriateness

The PPPA standards for child-resistance and adult-use-effectiveness are defined in 16 CFR 1700.15 and are based on the results of human performance tests described in 16 CFR 1700.20. When tested according to the methods, 80 percent of tested children (41-52 months old) (based on 200 children) must not be able to access the package. In addition, most packages must be accessible to 90% of tested adults aged 50-70. The exceptions to this are products that require metal containers with metal closures or aerosols. These products must be accessible to 90% of

adults tested aged 18 to 45 (16 CFR 1700.15(b)(2)(ii)). When this notice refers to child-resistance, it also means that the package meets the senior standard, unless otherwise specified.

Before issuing a regulation under the PPPA, the Commission must find that child-resistant packaging is technically feasible, practicable, and appropriate for the regulated products. 15 U.S.C. 1472(a)(2). "Technical feasibility" may be found when technology exists or can be developed to produce packaging that conforms to the standards described above. "Practicability" means that packaging complying with the standards can utilize modern mass production and assembly line techniques. Packaging is "appropriate" when complying packaging will adequately protect the integrity of the substance and not interfere with its intended storage or use.

The CPSC staff assessed the packaging of a range of products that may be included in the rule. Based on that assessment, the Commission believes that child-resistant packaging is technically feasible, practicable, and appropriate for hydrocarbon-containing products. There are currently three product categories that contain petroleum-derived hydrocarbons and for which child-resistant packaging is required (16 CFR 1700.14(a)(2), (7), and (15)). Child-resistant packaging that meets the standards is available and compatible with these hydrocarbon-containing

products. Many of the products that would be included in the recommended rule are similar in composition and use. This section will summarize technical information to support the findings for the variety of packaging types commonly used for hydrocarbon-containing products.

1. Continuous threaded packaging. Most packages that contain liquid products are currently sold with non-child-resistant continuous threaded (CT)(screw on) closures. These closures can be made of plastic or metal. This type of closure has been successfully modified to be child-resistant. There are several different types of child-resistant continuous threaded designs. The most common is the ASTM type IA closures. These are two-piece child-resistant closures that open by "pushing and turning." These types of closures are already being used on hydrocarbon-containing products, such as liquid furniture polish and mineral spirits. These and other types of continuous threaded closures are available from many different manufacturers. Stock closures are available and come in a variety of sizes, skirt lengths, and liner options. Plastic-on-metal closures are also available for products with solvents that may be incompatible with plastics.

Closures are also available that can accept brush applicators. Smaller sizes of these closures may have to be developed to accommodate the small bottles used for nail

dryers and nail moisturizers. These packages are very similar to those used for nail primers that contain methacrylic acid, for which the Commission recently required child-resistant packaging. 64 FR 32799 (June 18, 1999).

In most cases, the development of new closures or sizes will be unnecessary. However, modifications to the bottle neck finish and/or to the existing sorting and capping equipment may be necessary to change from non-child-resistant to child-resistant continuous threaded packaging.

(2) Dispensing packaging (inserts and flip-tops). The staff examined some cosmetic products that would be included in the recommended rule. Many baby oil, suntan oil, and bath oil products are currently packaged with dispensing capability. Several different packaging designs are being used, including restricted orifice plug inserts, flip-top dispensers, and finger pump dispensers.

The plug inserts and the flip caps both function by decreasing the orifice of the opening of the bottle. The plug insert fits flush with the opening of the bottle and does not interfere with the function of the closure. A child-resistant continuous threaded closure can replace the existing non-child-resistant closure as described above. The CPSC is not aware of any commercially available child-resistant flip-top closures for liquids. However, plug inserts with child-resistant closures can be substituted and

serve the same function. Plug inserts are compatible with mineral-oil-based cosmetics because several of the cosmetic products currently use plug inserts. Manufacturers may have to change bottle neck finishes or buy plug insert equipment if they are not currently using the inserts.

(3) Pump dispensers. Some suntan oils are available with finger pumps. The Commission recently addressed the child-resistance of finger pumps during the minoxidil rulemaking. In a comment in that rulemaking, a manufacturer said that it could make a child-resistant finger pump. The finger sprayer for minoxidil has to be metered to deliver a specific dose. This is not the case for hydrocarbon-containing products; therefore, the development of a finger sprayer for these products should be less complicated.

Companies using finger pumps have other options. Other products in this category use plug inserts as described above. In addition, there are several child-resistant overcaps being developed specifically for pump sprayers.

Some of these alternatives are more complex than others and would require more time and money to complete.

(4) Aerosols and trigger sprayers. Any product meeting the proposed requirements that is in aerosol, pump, or trigger sprayer packaging, and that is expelled as a stream, must be in a child-resistant package. Child-resistant aerosol overcaps are available on the market. There are

several designs that are also senior friendly. Since the overcaps do not come in contact with the products, compatibility of overcaps is not an issue.

For products that currently use a trigger sprayer, the CPSC is aware of a child-resistant trigger sprayer on the market and of several other designs under development. The Commission addressed the issue of child-resistant trigger sprayers during the fluoride rulemaking (63 FR 29949).

(5) Metal container closures. There are several designs, including snap caps and CT's, that are child-resistant and can be used with metal cans. These types of closures are currently being used on lighter fluids and some paint solvents. They are commercially available and compatible with hydrocarbons.

The CPSC concludes that the available data support the finding that it is technically feasible, practicable, and appropriate to produce special packaging for products that contain 10 percent hydrocarbons or more by weight with a viscosity less than 100 SUS at 100°F.

G. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such final regulation is issued, except that, for good cause, the Commission may establish an earlier effective date if it finds that it is in the public interest to do so. 15 U.S.C. 1471 note.

This rulemaking covers diverse groups of products with diverse packaging. Some of the packaging changes may be minimal, while others may be more extensive. For example, even though there are child-resistant packages readily available, changes from tool design to product-filling-line equipment may be required to replace some of the non-child-resistant packaging with various types of child-resistant packaging. In addition, there are multiple options available to manufacturers. Cost and consumer preference may play a role in determining which child-resistant feature is best suited to a product. Not all products in the same product category may take the same time to change to child-resistant packaging. However, the CPSC estimates that all of these packaging changes could be achieved within 1 year. Therefore, the Commission proposes an effective date of 1 year after publication of the final rule.

H. Economic Considerations

1. Introduction. Under the Regulatory Flexibility Act, the Commission must, when proposing a rule, either assess the impact of a regulation on small entities or certify that there will not be a significant economic effect on a substantial number of small entities. This section summarizes information about the potential impact on small businesses for both household chemical products and cosmetics and about the likely costs of packaging. After

considering the available information, and the factors referred to in 15 U.S.C. 1472(b), the Commission concludes that the proposed rule is reasonable.

Three trade associations provided comments on economic issues: the Arts & Creative Materials Institute ("ACMI"); CSMA; and CTFA. The comments focused on (1) costs of child-resistant packaging for specific types of packaging or products and (2) the effects of the proposal on some manufacturers because of the uniqueness of their products. Only a few individual companies provided comments relating to economic issues.

Below, the Commission provides information on the products likely to contain hydrocarbons with characteristics subject to the proposal. Hydrocarbon-containing products regulated under the FHSA and FDCA are discussed separately.

2. Hydrocarbon-containing products regulated under the FHSA.

(a) Market information. Hydrocarbon-containing products for consumer use that are regulated under the FHSA appear in many product categories, including adhesives, air fresheners, all purpose cleaners, all purpose lubricants, art materials such as markers, automotive fluids and cleaners, metal cleaners and polishes, paint solvents, shoe polishes, spot removers, and water repellents. The products are dispensed in aerosol, gel, liquid and solid form.

Based on a survey of just a "few" of its 400 member companies, the CSMA reported that an average of about 80 million units of hydrocarbon-containing products are sold annually. The CSMA said its members consider product formulation to be confidential business information. One individual company reported annual average sales of about 2 million units of hydrocarbon-containing products in bottles and cans. However, no information on product categories or formulations was provided.

Table I provides 1996 dollar and unit sales for some categories of automotive and household cleaning products that are likely to contain products formulated with hydrocarbons. However, the data do not reveal the share of the market attributable to hydrocarbon-containing products with characteristics that meet the criteria for the proposed rule or that are now packaged in child-resistant packaging.

Table 1

Selected Household Product Categories Likely to Contain Products Formulated with Hydrocarbons

Product Category	$ Sales (Millions)	Units* (Millions)	Average Retail Price ($)
Auto treatments/ other auto fluids	276.9	164.6	1.68
Auto waxes/polishes	218.5	83.9	2.60
Furniture polish	212.0	54.0	3.93
Floor cleaners, wax, wax removers	109.7	47.6	2.30
Shoe/vinyl polish, cleaner/wax	31.0	13.1	2.37
Specialty cleaner, polish	48.4	9.5	5.09
Household lubricants	13.6	7.1	1.92

Source: Share Facts, Find/SVP, 1996

*units are defined by Share Facts as 16 oz. equivalents

The Table 1 data do not include paints, coatings, or art materials. Although the National Paint and Coating Association ("NPCA"), which represents about half of the manufacturers or fillers of aerosol paints, noted that many aerosol paint formulas contain hydrocarbons, the association did not provide unit or dollar sales for these products. However, products packaged in aerosol containers that deliver a fine mist spray would not be subject to the proposed rule. Additionally, non-aerosol paints are not subject to the proposed rule because of their high viscosity.

The ACMI represents about 200 member companies that manufacture art and creative materials. ACMI surveyed its members and reported that less than 60 (exact number unknown) sell products that the proposal would cover. The association wrote that the products to which the proposal would apply are fairly specialized products used by adults (product types unspecified) in the art/hobby fields and that the products may not have a large sales volume. ACMI did not provide unit or dollar sales.

(b) Packaging costs. Neither the ACMI nor CSMA provided information on the potential costs of providing child-resistant packaging for their members' products. The ACMI

reported that its members did not provide sufficient cost-related information to respond to the request. ACMI wrote that some member manufacturers are voluntarily using child-resistant packaging for certain hazardous products and that since members "tend to support the proposal and have products already in child-resistant packaging, it would not appear to raise major cost obstacles."

While neither ACMI nor CSMA provided information on potential costs, it might be noted that incremental costs for child-resistant packaging typically range from $0.005 to $0.02 per package. For products using a recently developed child-resistant trigger spray, incremental costs will amount to about $0.025 per package.

(c) Small business effects. The Commission does not know the universe of companies that would be affected by the proposed requirement. At least 1,500 large and small companies were notified of the proposal through trade associations and individual mailings. However, the responses to the ANPR provided no information indicating that small businesses would be significantly affected by the proposed child-resistant-packaging requirement. Additionally, there are several reasons to believe that the proposed rule would not have a significant impact on affected companies. Some manufacturers of household products that are subject to the proposal are currently providing child-resistant packaging. Manufacturers of

household products typically have diverse product lines that also include product formulations that would not be included under the proposal. Thus, the number of products that would require child-resistant packaging may represent a small proportion of a firm's production. Finally, the firms would be able to exhaust existing inventory, since the rule would not apply to products packaged before the effective date.

Only two individual small companies commented on the packaging costs that would be incurred to convert their products to child-resistant packaging. While both indicated there would be an economic burden, neither provided specific cost information. The product of one company is packaged in an aerosol container and delivers a fine mist spray; the product of the other company is packaged in a tube with a restricted-flow moist-fiber applicator tip. Neither of these package types would be covered under the proposed rule; thus, the proposal will have no effect on these companies.

Based on the response to the ANPR, and the wide availability and relatively small incremental costs of child-resistant packaging, the Commission certifies that the proposed rule, if promulgated and as it relates to products regulated under the FHSA, will not have a significant economic effect on a substantial number of small entities.

3. Hydrocarbon-containing products regulated under the FDCA.

(a) Market information. Mineral oil, a hydrocarbon available in a wide range of viscosities, is used in a number of personal care products regulated under the FDCA. Products containing mineral oil and having a low viscosity, such as some baby oils, bath, massage, and sensual aroma oils, eye makeup removers, and nail care and sun care preparations, would also be covered under the proposed rule. While many of these products are typically sold separately, others are sold as part of a gift box that includes several items, for example, fragrant bath oil packaged with a soap and powder. The products may have aerosol, foam, gel, liquid, lotion, and solid formulations, and use a variety of delivery systems.

The CTFA, which represents about 275 manufacturers of cosmetic products, commented that most cosmetics product categories containing mineral oil are marketed in solid form and thus do not present an aspiration hazard. The association also noted that only a few of the cosmetics in liquid form would be subject to the contemplated child-resistant packaging requirement. This is because most exceed the viscosity limit and/or contain less than 10% hydrocarbons.

Many baby oil products are available in cream, lotion, and gel formulations. The proposed rule will not affect these products because of their high viscosity. Similarly, the proposal will not affect many sun care products because

of their high viscosities (creams, gels, lotions, solid sticks) or because they do not contain hydrocarbons.

In response to the ANPR, CTFA sent a survey to over 200 representatives of member companies and received only 15 completed surveys. CTFA reported that some companies returned the survey stating that they used no hydrocarbons, they were not currently marketing subject products, or their products were not for household use. In addition to products containing hydrocarbons, most manufacturers of cosmetics typically have extensive product lines and use various formulations without hydrocarbons. The association summarized member comments and provided information only by product category, without identifying brands or companies. There was no indication as to whether the responding companies were "small" or "large" businesses. Only manufacturers of baby oil provided market share and unit sales data in response to the survey. Based on these data, CPSC staff estimates the annual sales of baby oil at about 35 million units.

For all cosmetic product categories, Drug Topics (May 5, 1997) indicated that sales amounted to $2.9 billion and 911.5 million units in 1996. No breakout by type of product was given. However, the trade publication Happi (March 1996) reported that sun care products, a cosmetics category with some hydrocarbon-containing preparations, had $393.8 million in sales (almost 70 million units) in drug, food,

and mass merchandise stores in 1995. However, Happi did not provide a breakout of the products that make up the sun care category, which includes sunscreens/sunblocks, self-tanners, and after-sun preparations.

(b) Packaging costs. Packaging for cosmetic products that may contain mineral oil currently includes finger press and pump dispensers, continuous threaded closures, flip tops with restricted orifices, finger spray pumps, and trigger sprays. Some nail care products are packaged with a plug insert restricted-neck fitting in the bottle's neck to remove excess product from the applicator brush.

According to a leading closure manufacturer, incremental costs for some types of child-resistant packaging that can be used for baby oil, sun care, and other mineral-oil-containing cosmetics are about $0.01 per unit (depending upon size, quantity ordered, and color). These package types include a commercially available package with a child-resistant closure and a restricted-neck fitting, and a dispensing cap with a flip top is under development. CTFA commented that a marketer of eye makeup remover reported the incremental cost for child-resistant packaging for the company's product would amount to 1.5 cents. Additionally, the incremental cost for a recently developed child-resistant trigger spray is about $0.025 per unit.

There is an unknown quantity of nail care products that the proposal may affect. Samples of mineral-oil-containing

cuticle and nail oils CPSC staff examined were packaged with 13-20mm diameter neck finishes on bottles with built-in applicator brushes. They contain 0.4 to 1.0 oz of product. It may be necessary for some suppliers to change the closure and bottle finish in order to accommodate potentially available child-resistant packaging. There are at least two U.S.-based packaging manufacturers that could develop child-resistant closures with applicator brushes. No information is available regarding the incremental cost of such packaging.

In addition to the incremental cost of child-resistant packaging, manufacturers may also incur one-time start-up costs. Initial costs vary widely according to the product and to the extent of package redesign. CTFA provided estimates of one-time packaging costs based on the member survey noted earlier. The estimates for child-resistant packaging for baby oil, bath oil, and sunscreen products ranged from $163,000 to $1.5 million and, depending upon manufacturer, included research and development, new bottle molds, new custom-designed caps, and new tooling for product-filling lines. No specific information was provided to support these costs.

One manufacturer, providing comments independent of the CTFA, estimated the start-up costs for child-resistant packaging for baby oil at $122,000 for tooling and changing parts, assuming that only the closure changed and bottle

shapes and sizes were not affected. The estimates for tooling and changing parts for child-resistant packaging for a tanning oil, moisture lotion, and bath oil ranged from $6,100 to $85,100.

(c) Small business effects. The concerns of some cosmetics manufacturers center on the need for custom-design packaging, especially for products with small markets, and on the effect of using child-resistant packaging on exports. As noted earlier, CTFA did not provide information regarding the identity of responding companies; thus, the Commission does not know if these manufacturers are small businesses. The high start-up cost estimates for custom-design child-resistant packaging were discussed above. One unidentified CTFA member commented that "packaging aesthetics is an integral element of cosmetics and [is] a key factor in packaging decisions and ultimately, consumer purchases." Several companies indicated that they would be forced to discontinue various products if child-resistant closures were required, because product sales would not support the costs of providing the packaging. Data regarding types of product, formulation, sales volume, and projected packaging costs were not provided.

A number of CTFA member companies also expressed concerns regarding exports of child-resistant packaged cosmetics. According to CTFA, packaging requirements for cosmetics would adversely impact global sales because "of a

negative consumer perception in foreign countries about the safety of the U.S. product with a child-resistant closure versus the foreign competitor's product that is not child resistant." The association also commented that a foreign competitor's packaging cost could be lower than the U.S. product with a child-resistant closure and that consumers would buy the cheaper product in many cases. The association did not provide comparisons between foreign and domestic costs or data regarding the value of exports that the proposal may impact. The proposed rule does not require companies that export affected cosmetic products to use child-resistant packaging for their exports.

CTFA reports that one member company manufacturing a massage oil packaged with a continuous threaded closure and a restricted flow opening would drop the product rather than provide child-resistant packaging. According to CTFA, the product, selling at retail for $26 (6.7 oz) has low sales volume that does not make it "worth the investment to refit with special packaging." No estimate of the magnitude of the investment for child-resistant packaging was provided. Additionally, CTFA reported that one manufacturer of nail products said it would discontinue two products if child-resistant packaging were required. A second nail-product manufacturer anticipated that child-resistant packaging would cost several thousand dollars for custom cap retooling and result in a 40% increase (unstated dollar value) in

ongoing packaging costs. The size of these businesses is unknown.

The Commission does not know the universe of companies that would be affected by the proposed requirement for child-resistant packaging for products regulated under the FDCA. The Commission requests that suppliers, especially small businesses and organizations representing small businesses, provide specific information about their products and the effect the proposed rule would have on them. The responses to the ANPR did not indicate that many small businesses would be affected. The wide availability and relatively small incremental costs of child-resistant packaging relative to the retail price of cosmetic products suggest that few firms should have a significant economic burden.

Based on the economic information available on the proposed rule affecting products regulated under the FDCA, the Commission certifies that the proposed rule, if promulgated, would not have a significant economic effect on a substantial number of small entities.

I. Preliminary Environmental Assessment

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 has preliminarily assessed the possible environmental effects associated with the proposed packaging

requirements for household products that contain hydrocarbons of low viscosity.

The Commission's regulations at 16 CFR 1021.5(c)(3) state that the rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. Preliminary analysis of the impact of this proposed rule indicates that child-resistant packaging requirements for the production of marketers of low-viscosity hydrocarbon-containing products under the proposed rule will have no significant effects on the environment. The manufacture, use, and disposal of child-resistant closures will present the same environmental effects as do non-child-resistant closures.

J. Executive Orders

This proposed rule has been evaluated in accordance with Executive Order No. 13,083, and the rule raises no substantial federalism concerns.

Executive Order No. 12,988 requires agencies to state the preemptive effect, if any, to be given the regulation. The preemptive effects of these rules is established by Section 7 of the PPPA, which states:

> (a) ... whenever a standard ... under [the PPPA] applicable to a household substance is in effect, no State or political subdivision of a State shall have any authority either to establish or continue in effect, with respect to such household

> substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the [PPPA] standard [and exemption, etc.].

15 U.S.C. 1476(a).

Subsection (b) of 15 U.S.C. 1476 provides a circumstance under which subsection (a) does not prevent the Federal Government or the government of any State or political subdivision of a State from establishing or continuing in effect a special packaging requirement applicable to a household substance for its own [governmental] use, and which is not identical to the standard applicable to the product under the PPPA. This occurs if the Federal, State, or political subdivision requirement provides a higher degree of protection from such risk of injury than the consumer product safety standard.

Subsection (c) of 15 U.S.C. 1476 authorizes a State or a political subdivision of a State to request an exemption from the preemptive effect of a special packaging requirement. The Commission may grant such a request, by rule, where the State or political subdivision standard or regulation (1) would not cause the household substance to be in violation of the Federal standard, (2) provides a significantly higher degree of protection from the risk of injury than does the Federal standard and (3) does not unduly burden interstate commerce.

K. TRADE SECRET OR PROPRIETARY INFORMATION

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

The Commission's staff will then make a determination of whether the information is trade secret or proprietary information that cannot be released. That determination will be made in accordance with applicable provisions of the CPSA; the Freedom of Information Act ("FOIA"), 5 U.S.C. 552b; 18 U.S.C 1905; the Commission's procedural regulations at 16 CFR Part 1015 governing protection and disclosure of information under provisions of FOIA; and relevant judicial interpretations. If the Commission concludes that any part

of information that has been submitted with a claim that the information is a trade secret or proprietary is disclosable, it will notify the person submitting the material in writing and provide at least 10 calendar days from the receipt of the letter for that person to seek judicial relief. 15 U.S.C. 2055(a)(5) and (6); 16 CFR 1015.19(b).

List of Subjects in 16 CFR Part 1700.

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

Effective date. The Commission proposes that the rule become effective 1 year after publication of the final rule. This period will allow manufacturers to make any changes in their production needed to comply with the standard without unduly delaying the safety benefits expected from the rule.

For the reasons set out in the preamble, the Commission proposes to amend 16 CFR 1700.14(a) as set forth below.

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

Authority: 15 U.S.C. 1471-1476.

Secs. 1700.1 and 1700.14 also issued under 15 U.S.C. 2079(a).

2. In § 1700.14(a), add new paragraph (30) to read as follows:

(30) Hazardous substances containing low-viscosity hydrocarbons. All prepackaged nonemulsion-type liquid household chemical products that are hazardous substances as defined in the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261(f)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

(i) Products in packages in which the only non-child-resistant access to the contents is by a spray device (e.g., aerosols or pump- or trigger-actuated sprays) that expels the product solely as a mist. This exemption includes products that expel the product as a mist in their as-sold condition, but that can be modified by adding a tube to expel the product as a stream.

(ii) Writing markers and ballpoint pens exempted from labeling requirements under the FHSA by 16 CFR 1500.83.

(iii) Products from which the liquid cannot flow freely, including but not limited to paint markers and battery terminal cleaners.

For the purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbon in the product is

calculated by adding the percentage by weight of the individual hydrocarbon components.

3. In § 1700.14(a), add new paragraph (31) to read as follows:

(31) Drugs and cosmetics containing low-viscosity hydrocarbons. All prepackaged nonemulsion-type liquid household chemical products that are drugs or cosmetics as defined in the Federal Food, Drug, and Cosmetics Act (FDCA) (21 U.S.C. 321(a)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

(i) Products in packages in which the only non-child-resistant access to the contents is by a spray device (e.g., aerosols or pump- or trigger-actuated sprays) that expels the product solely as a mist. This exemption includes products that expel the product as a mist in their as-sold condition, but that can be modified by adding a tube to expel the product as a stream.

(ii) Products from which the liquid cannot flow freely, including but not limited to makeup removal pads.
For the purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbon in the product is

calculated by adding the percentage by weight of the individual hydrocarbon components.

Dated: _____, 1999.

_____
Sadye E. Dunn, Secretary
Consumer Product Safety Commission