On January 21, 1986, American Home Products Corporation (Petitioner) filed a petition pursuant to Rule 2.51 of the Commission's Rules of Practice, 16 CFR 2.51, and Paragraph III of the order in question to reopen the proceeding and modify the final cease and desist order entered against it by the Commission on June 9, 1970, in Docket No. 8641 (77 F.T.C. 726).

The final order in this matter was the product of extended litigation concerning therapeutic advertising claims for Preparation H Ointment or Suppositories. The order effectively proscribes all therapeutic advertising claims for Preparation H Ointment or Suppositories, or any other non-prescription drug product for the treatment or relief of hemorrhoids or any of its symptoms, except for three specifically enumerated claims. The three claims permitted under the order are (1) that the use of the product will help reduce swelling of hemorrhoidal tissue caused by edema, infection, or inflammation; (2) that the use of the product will help reduce swelling of hemorrhoidal tissue by lubricating the affected area; and (3) that use of the product will afford temporary relief of pain and itching of hemorrhoidal tissue in many cases. The order concludes with a proviso (Part III) that if the Food and Drug Administration (FDA) should approve for such products any other claims as permissible in labeling, respondent may petition for a modification of the order on that ground.

Subsequently, the Food and Drug Administration (FDA) undertook a comprehensive review of the safety and effectiveness of over-the-counter (OTC) drug products under the "Drug Amendments of 1962" to the "Federal Food, Drug and Cosmetic Act." As part of this review, the FDA appointed panels of independent experts in medicine and pharmacology to review the available literature and data and evaluate the safety and effectiveness of ingredients used in OTC products. After completing their evaluations the panels reported their findings and conclusions concerning the classes of OTC products evaluated and recommended appropriate labeling claims for each of the classes of OTC products reviewed. The labeling recommendations are incorporated into proposed monographs which, after a three step procedure designed to determine appropriate revisions, if any, will be promulgated as final monographs or rules which will govern the labeling claims of OTC products. One such panel reviewed and evaluated OTC hemorrhoidal (anorectal) drug ingredients. Its findings and conclusions and recommendations and a proposed monograph for OTC anorectal drugs were published in the **Federal Register** on May 27, 1980. (45 FR 35575.)

It is this proposed monograph that forms the basis for Petitioner's requested modification. Under this proposed monograph OTC anorectal drug ingredients are classified into several groups on the basis of their pharmacologic action, such as local anesthetics, vasoconstrictors, protectants, and counterirritants. An OTC anorectal drug can be classified as a protectant if, for example, it contains cocoa butter 50 percent or greater per dosage unit or it contains white petrolatum USP 50 percent or greater per dosage unit. An OTC anorectal drug meeting these percentage requirements would be entitled under the proposed monograph to be labeled with certain specific protectant claims.

Petitioner claims that Preparation H Ointment contains 72.8% petrolatum and that Preparation H Suppositories contains 79.5% cocoa butter thereby qualifying those products as protectants under the proposed monograph. As a consequence, Petitioner argues that it should be entitled to make as labeling claims those claims permitted by the FDA under the proposed monograph. However, the Commission's final order prohibits the use of a number of these claims and Petitioner asserts this prohibition places it at a competitive disadvantage with OTC anorectal protectant drug products marketed by others. As a consequence, Petitioner has requested that the final order be modified to allow it to make all advertising claims it is allowed by the proposed monograph to use in its labeling for Preparation H Ointment or Suppositories.

We agree. In prior decisions, we have held that proposed FDA monographs may be relied on as a reasonable basis for performance claims. *AHC Pharmacal, Inc.*, 101 F.T.C. 40, 43 (1983); *Thompson Medical Co., Inc.*, 104 F.T.C. 648, 826 (1984); *Chesebrough-Pond's Inc.*, Docket No. C-602 (November 25, 1985). Such relief is particularly appropriate where, as here, the advertising claims would be dependent on their acceptability as labeling claims. Based on the foregoing, we conclude that Petitioner has made the requisite showing for a reopening of the proceeding and a modification of the order under Rule 2.51 and Paragraph III of the final order. Respondent has asked that Part III of the order be modified to make clear that it may make claims in advertising that the FDA has allowed in labeling.

It is therefore ordered that the proceeding as hereby reopened and that Paragraph III of the final order issued June 9, 1970, in Docket No. 8641 be, and it hereby is modified to read as follows:

"III. This Order is not intended to nor does it prohibit respondent from making any representations for non-prescription drug preparations for the treatment or relief of hemorrhoids or any of their symptoms which the Food and Drug Administration has determined, in the course of its over-the-counter drug review, relate to conditions for which the drug preparation is generally recognized as safe and effective and not misbranded. In the event that respondent at any time in the future markets any non-prescription drug preparation for the treatment of relief of hemorrhoids or any of its symptoms for which it desires to make any of the representations now prohibited under Paragraph I of the order, it may petition the Commission for a modification of the order. Such petition shall be accompanied by a showing that the representation is not false or misleading within the meaning of the Federal Trade Commission Act."

By the Commission. Commissioners Oliver and Strenio did not participate.

Issued: May 22, 1986.

Emily H. Rock,

Secretary.

[FR Doc. 86-12652 Filed 6-4-86; 8:45 am]

BILLING CODE 6750-01-M

RAILROAD RETIREMENT BOARD

20 CFR Part 395

Regulations Under Title VII of the Regional Rail Reorganization Act

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board amends its regulations pertaining to reviews and appeals of initial determinations under the benefit schedules promulgated by the Secretary of Labor pursuant to section 701 of the Regional Rail Reorganization Act. The benefit schedules are administered by the Board.

EFFECTIVE DATE: June 5, 1986.

FOR FURTHER INFORMATION CONTACT: Arthur A. Arfa, Assistant Director of Hearings and Appeals, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611, (312) 751-4793 (FTS 387-4793).

SUPPLEMENTARY INFORMATION: Section 395 of the Board's rules provided for certain time limits during which a claimant who wished to appeal an initial adverse determination might file such an appeal. The regulations were not precise as to when the time period

began to run since they used the phrase, "communicated" to the claimant as the start of the appeal time period. The use of that phrase makes it unclear whether the appeal period starts on the date the notice of the decision is sent to the claimant or when it is received by the claimant. The amendment to the regulation clarifies that the appeal period begins to run from the date the notice is mailed.

The Board has determined that this is not a major rule under Executive Order 12291. Therefore, no regulatory analysis is required. There are no information collections associated with this rule.

A notice of proposed rulemaking was published in the Federal Register on February 24, 1986 (51 FR 6422). No comments were received from the public.

List of Subjects in 20 CFR Part 395

Employee benefit plans, Employee protection benefits, Railroad employees, Railroad Retirement.

PART 395—[AMENDED]

Title 20 CFR Part 395 is amended as follows:

1. The authority citation for Part 395 is revised to read:

Authority: 45 U.S.C. 362(1); 45 U.S.C. 797.

§ 395.9 [Amended]

2. Section 395.9 is amended by adding at the end of paragraphs (c)(1) and (d)(1) the following new sentence which reads as follows: Notice shall be deemed to have been communicated to the claimant when it is mailed to the claimant at the latest address furnished by him or her.

Dated: May 28, 1986.
By Authority of the Board.
Beatrice Ezerski,
Secretary to the Board.

[FR Doc. 86-12631 Filed 6-4-86; 8:45 am]
BILLING CODE 7905-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 740

[Docket No. 76N-0486]

Cosmetic Product Warning Statements: Establishment of Effective Date for Label Caution Requirement on Children's Foaming Detergent Bath Products; Response to Comments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has completed its reconsideration of 21 CFR 740.17, a regulation that would require that directions for safe use and a caution statement appear on the label of foaming detergent bath products. The agency announced its intention to reconsider this regulation in the Federal Register of February 13, 1983 (48 FR 7203). Upon reconsideration, FDA has decided to take the following actions: (1) FDA is denying the petitions of the Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), and of the Independent Cosmetic Manufacturers and Distributors (ICMD) to revoke the regulation for children's foaming detergent bath products or any such product whose label does not make clear that it is intended for use exclusively by adults. (2) FDA is granting these petitions to revoke the regulation for those products whose labels make clear that they are intended for use exclusively by adults. (3) FDA is establishing a new effective date for the regulation except with respect to those products whose label makes clear that they are intended for use exclusively by adults.

DATES: Effective June 5, 1987. All foaming detergent bath products except those intended for use exclusively by adults that are initially introduced or initially delivered for introduction into interstate commerce on or after June 5, 1987, shall comply with this regulation. FDA is continuing the interim stay of the effective date of 21 CFR 740.17 until June 5, 1987.

FOR FURTHER INFORMATION CONTACT: Heinz J. Eiermann, Center for Food Safety and Applied Nutrition (HFF-440), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1530.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 19, 1980 (45 FR 55172), FDA published a final regulation (21 CFR 740.17) that requires that labels of foaming detergent bath products bear a prescribed caution statement and provide adequate directions for safe use. The statement cautions that excessive use of, or prolonged exposure to, foaming detergent bath products may cause irritation to the skin and the urinary tract. It urges consumers to discontinue use of such products if rash, redness, or itching occurs and to consult a physician if irritation persists.

Foaming detergent bath products are commonly identified and recognized by consumers as "bubble baths" or "foaming bath oils." These products are also known by other names such as "foaming bath," "milk foam bath," and "foaming bath powder." To avoid any confusion as to which products are subject to this regulation, FDA has adopted the general term "foaming detergent bath product" for these types of products. FDA has modified § 740.17 to reflect this new terminology.

Section 740.17 was to have gone into effect on August 19, 1981. However, on June 1, 1981, the agency issued a press release announcing its intention to stay this regulation. On February 18, 1983, FDA announced an interim stay of the effective date of the regulation (48 FR 7169).

In addition to issuing the interim stay, FDA proposed to stay the effective date of the regulation while it reconsidered the labeling requirement (48 FR 7203). The agency stated that it was still concerned about the adverse effects of foaming detergent bath products on children when not properly used, but that the petitions of CTFA and ICMD to revoke the labeling requirement had raised issues that merited a full review of the regulation.

In the February 18, 1983 notice of proposed stay, FDA invited interested persons to submit comments, data, or other information on how consumers could be informed of the risks associated with the use of foaming detergent bath products and effectively protected from irritation to the skin and urinary tract that might result from the misuse of these products. The agency asked that comments specifically address the following questions:

1. How may consumers be informed of the risks associated with the use of foaming detergent bath products other than by means of a required label caution statement and directions for safe use?

2. Did the reported adverse reactions associated with foaming detergent bath products marketed for adult use occur predominantly in adults or children?

3. Would a revised regulation applicable only to products intended for use by children provide adequate consumer protection taking into account the possibility of use (or misuse) of adult products as children's products?

4. What costs would be associated with the caution labeling requirements of § 740.17 or the alternatives suggested in comments?

FDA received 17 comments during the comment period on the proposal. Four comments were from consumers, three were from physicians, one was from a consumer organization, two were from cosmetic trade associations, and seven were from cosmetic manufacturers. Six comments were in favor of a caution labeling requirement, one comment recommended that cosmetic foaming

detergent bath products be banned, and 10 comments were against the regulation. None of the comments suggested alternatives to requiring caution labeling, and none responded in a substantive manner to the questions about the risks of foaming detergent bath products to adults or about whether revised regulations would adequately protect children from use of adults' products. Three comments gave estimates of the costs to manufacturers of implementing the caution labeling as required by § 740.17.

FDA has now completed its review of the regulation, as well as of the petitions and of the comments that it received on the proposal to stay the regulation. Based on this review, the agency finds that there is a continuing cognizable risk for children from improper use of foaming detergent bath products. The agency has therefore decided to deny the petitions to revoke the caution labeling regulation except for products whose labels make clear that they are intended for use exclusively by adults.

FDA considers all products not labeled as intended for use exclusively by adults to be intended for use by children. Label statements that would identify products as being intended for use exclusively by adults would include: "Keep out of reach of children" and "For adult use only."

An explanation for the agency's decision on children's foaming detergent bath products, a description of the points made in the petitions and in the comments on the petitions, and the agency's responses to these points follow.

I. The Petitions and Comments Do Not Provide a Basis for Revoking the Rule

A. Need for the Regulation

1. The petitions and a number of the comments (FDA will hereinafter refer to the petitions and the comments on those petitions collectively as "the comments") restated arguments that FDA had discussed in the preamble to the final rule published in the **Federal Register** of August 19, 1980 (45 FR 55172–55173). The comments asserted that the number of injury complaints cited by FDA was not large enough, and that the reported injuries were not serious enough, to demonstrate a hazard warranting a label warning. These comments also stated that the annual numbers of reported adverse reactions had been decreasing since 1973. Two comments claimed that the risk of injury from use of foaming detergent bath products is insignificant. In support of this claim, these comments cited the July 1, 1977, to June 30, 1978, statistics on cosmetic injuries reported by hospital emergency rooms into the National Electronic Injury Surveillance System (NEISS) of the Consumer Product Safety Commission. Two manufacturers of foaming detergent bath products submitted their animal testing data as evidence of the safety of these products.

FDA disagrees with the argument that the consumer injury data do not demonstrate a hazard warranting a caution statement and directions for safe use on labels of foaming detergent bath products. The information presented in the preambles of the proposed and final regulations fully documented the need for these requirements.

There was a decrease during the mid-70's in the recorded number of complaints from consumers about foaming detergent bath products because of a change in complaint forwarding policy by district offices. FDA explained in the preambles to both the proposal (42 FR 5368) and the final rule (45 FR 55172) that the reason for the significantly higher number of complaints before 1973 was the press and radio solicitation by the Federal Trade Commission of reports of adverse reactions from consumers. The fact that a large producer of these products voluntarily added a caution statement to the label of its foaming detergent bath products in 1974 may also have contributed to the decline in consumer complaints. The decrease in complaints that occurred between 1975 and 1978 has not continued. The rate of these complaints in relation to the total numbers of complaints recorded annually has averaged 1.98 percent (standard deviation of 0.75 percent) since 1975. The adverse reaction data submitted to FDA by cosmetic manufacturers as part of the voluntary registration program show averages of 1.22 (standard deviation of 0.57) adverse reactions per million units distributed for the years 1974 to 1976 and 1.66 (standard deviation of 0.51) for the years 1982 through 1984.

The seriousness of the adverse reactions is reflected in part in the relatively high percentage of injuries reported that required medical attention. For the years 1979 through 1984, an average of 43.8 percent of the injuries associated with foaming detergent bath products that were reported under the voluntary industry reporting program required medical treatment, whereas the average for all product categories for the same time period was 17.9 percent (standard deviation of 11.3 percent). After feminine deodorant products (55.6 percent) and fragrance sachets (45.4 percent), both of which have low numbers of experiences reported, which may produce distortion, "bubble bath products" is the product category with the highest rate of injuries requiring medical attention. Additionally, of the 234 consumer complaints received by FDA associated with foaming detergent bath products between 1970 and 1984, 38 percent concerned urogenital disorders.

The NEISS data of July 1, 1977, to June 30, 1978, which were submitted by two comments in support of the argument that foaming detergent bath products do not present a health risk that requires caution labeling, usually reflect acute toxic manifestations, resulting from accidental product misuse, that are treated at the reporting hospital emergency rooms. As discussed in the **Federal Register** notices during the rulemaking, the injuries associated with foaming detergent bath products are not likely to result from just one exposure to this type of product, and consumers are not expected to seek treatment at an emergency room for a gradually worsening skin rash or urogenital irritation.

Equally inapplicable are the animal testing data for eye or skin irritation submitted by two manufacturers of foaming detergent bath products. The tests from which these data were obtained are typical for assessing the safety of detergent-containing products before conducting human studies. However, the data from these tests have no relevance to this proceeding because they are not indicative of the adverse reactions that may occur in consumers under the conditions of misuse that the caution labeling regulation is intended to address.

2. Of the three physicians who commented on the proposed stay of the effective date of the foaming detergent bath labeling regulation, two reported treating numerous cases of urogenital irritation or infection that were associated with foaming detergent bath products. Both of these physicians were pediatricians. One recommended that foaming detergent bath products be banned, and the other favored caution labeling. The third comment, from a physician principally involved in consumer product safety evaluation, described several cases of skin and urogenital irritation that occurred during the testing of foaming detergent bath products but expressed the opinion that the warning was not justified.

FDA has carefully considered the views of each of these three physicians along with other available information and concludes that, on balance, the medical opinions that have been submitted to the agency support the

need for the regulation. The medical observations reported by the two pediatricians complement those reported by the five physicians who commented on the proposed rule (see 45 FR 55172). Accordingly, seven of the nine physicians who have commented have supported the agency's finding that foaming detergent bath products can cause adverse reactions, particularly when misused. The caution statement and directions for safe use are justified as a means of preventing that misuse.

3. Two comments stated that the requirement of a caution statement and directions for safe use will undermine the impact of warnings on products that present serious risks, destroy the incentive to develop the least irritating product, and encourage use of noncosmetic substitute products, such as household detergents, in baths. Other comments asserted that manufacturers had cooperated with FDA to reduce the possibility of adverse reactions by reformulating products and voluntarily including caution language in labeling about the consequences of misuse. These comments claimed that the regulation threrefore was unnecessary.

Neither of these comments provides any evidence to support the predictions that they make. The need for both caution labeling and directions for safe use to prevent misuse and serious injury is fully documented in the record of this proceeding. The agency is not aware of any data that indicate that cosmetic manufacturers would stop striving to market the safest product possible, or that consumers would substitute household detergents for cosmetic foaming detergent bath products, if the agency puts this regulation into effect.

The agency reviewed all cosmetic foaming detergent bath product formulations voluntarily registered with FDA under 21 CFR Part 710 during the past 10 years. Of the formulation changes registered with FDA, few involved foaming agents. Furthermore, FDA is aware of only one cosmetic manufacturer that has voluntarily included caution language in the labels of its foaming detergent bath products. That manufacturer informed FDA that it also made several formulation changes in its products, including elimination of alkylarylsulfonate, in an effort to reduce those products' potential for irritating the skin.

4. One comment argued that the regulation is a burdensome and unnecessary rule that conflicts with the regulatory policy of Executive Order 12291.

FDA has carefully considered this comment. As the agency's responses in this document make clear, there is a need to caution users of foaming detergent bath products that injuries to children may result from the misuse of those products. Moreover, as explained in the discussion that follows, the costs of this regulation are low and therefore not burdensome. Nonetheless, to ensure that the obligations imposed by this regulation are no greater than necessary to protect children, FDA is not requiring the caution on those products whose labels make clear that they are intended for use exclusively by adults.

B. Labeling Costs

5. Four comments addressed the issue of the costs to cosmetic manufacturers of complying with the requirements of § 740.17. One manufacturer of foaming detergent bath products reported a cost of $35 per label for new silk screens and, because of the many brands involved, a total cost to the firm of $50,000 to $55,000. The manufacturer of a line of children's foaming detergent bath products estimated the total cost for its various label changes to be almost $50,000. A comment from a trade organization stated that the cost of compliance with the regulation will be about $10,000 for an existing product and $12,000 to $15,000 for a new product. This comment also argued that small firms would probably incur greater absolute, as well as comparative, costs than large firms because large firms would benefit from economies of scale. A trade organization reporting information obtained from two of its member firms stated that one firm estimated the cost to be between $50,000 and $55,000. The other firm estimated the cost to be in excess of $250,000.

FDA has conducted an independent study of the expected costs of compliance and has concluded that the total cost to industry will be approximately $300,000. This total includes the cost of changes in artwork, the expense of preparing new film representations for printing plates, and administrative costs for each producer of foaming detergent bath products. The agency has not, however, considered decreased revenues for producers of foaming detergent bath products as a cost. FDA concludes that any reduction in use of foaming detergent bath products that occurs will be toward safe levels, so that decreases in revenues cannot be counted as a true economic cost. Details of the FDA study can be found in the "Threshold Assessment for the Modification and Withdrawal of Stay of the Foaming Detergent Bath Products Caution Statement Regulation," which is on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

Based upon the FDA study of compliance costs, and on the study of the costs of a one-time label change done by A.D. Little, Inc., for FDA in 1981, FDA can find no basis for some of the cost estimates submitted by industry. In particular, it is not clear why, as one comment asserted, the costs for a new product would be $12,000 to $15,000. Except for administrative costs, there should be no compliance cost for a new product because the label would be designed from the outset in compliance with existing labeling requirements. Furthermore, given all information currently available, FDA can find no substantive evidence that the cost for any one firm approaches the $250,000 figure cited by one company.

Considering that consumers are likely to benefit from caution labeling by having fewer adverse reactions to foaming detergent bath products, less severe injuries, less bodily suffering, and fewer medical expenses, the agency concludes that the cost of implementing the labeling requirement is well justified and is neither burdensome nor inflationary.

C. Procedural Issues

6. One comment argued that, in the preamble to the final regulation, the agency had failed to address certain important comments. According to the comment, FDA had not addressed the issue of exclusion of adult foaming detergent bath products, liquid products, and products in small size containers from the coverage of the rule; the argument that alkylarylsulfonates were the apparent source of adverse reactions; or the assertion that the complaint levels had decreased following reduced use of alkylarylsulfonate.

FDA disagrees with this comment. In the final rule, the agency addressed each of the contentions mentioned in the comment. FDA stated that the marketing of foaming detergent bath products in small packages does not offer the agency assurance that adverse reactions will not occur (45 FR 55174). It stated that the adverse reaction data in its consumer complaint files did not permit it to conclude that liquid products and products intended for use by adults did not cause a significant number of adverse reactions (*id.*). With regard to alkylarylsulfonate, a surface-active agent, the agency referenced its discussion of this ingredient in the preamble to the proposed regulation and explained why it was not persuaded that this ingredient alone was

responsible for the high complaint rates (45 FR 55173). Finally, in the final rule, the agency explained why it did not agree with claims that the rate of adverse reactions to foaming detergent bath products had declined since 1973 (*id.*). This explanation also responds to the assertion that complaint levels had decreased following reduced use of alkylarylsulfonate in foaming detergent bath products. For all these reasons, FDA finds that there is no basis for the comment's claim that the agency had failed to address important comments.

II. Continuing Need for Caution on Children's Products

As part of its reconsideration of this regulation, FDA considered not only whether the evidence establishes a need for the regulation, but also whether it establishes a basis for treating foaming detergent bath products intended for use by adults differently than those intended for use by children. As discussed above, in the February 18, 1983, notice, FDA specifically asked for comments on the latter question. FDA finds that the evidence establishes that consumer complaints are associated with both types of products, and that therefore there is an appropriate basis in the record for requiring adequate directions for safe use and some type of caution on both types of products.

FDA reviewed the foaming detergent bath product-related consumer complaint statistics and the adverse reactions voluntarily filed by some cosmetic manufacturers under 21 CFR Part 730. Between 1970 and 1984, FDA received 234 foaming detergent bath product-related consumer complaints. Sixty-seven percent of those complaints were related to products intended for use by children, and 24 percent were related to products intended for use by adults. The other complaints could not be classified.

FDA's review of the data voluntarily submitted by cosmetic manufacturers between 1979 and 1984 revealed that of the 345 reported adverse reactions to foaming detergent bath products, 87 percent were associated with adults' products, 5 percent were associated with children's products, and 8 percent were associated with products that could not be classified.

The two sets of statistics thus contradict each other, and FDA could not conclude that only one category of products was predominantly responsible for the reported adverse reactions. A review of the voluntarily registered foaming detergent bath formulations and of the technical trade literature also provided no evidence of distinctive differences in composition (other than generally higher fragrance concentrations in adult products) that would indicate that one type of product has a significantly greater potential for injury when misused than the other. It should be noted, however, that neither the data in FDA's files on consumer complaints nor those in the voluntary registration files permitted statistical evaluation of whether the adverse reactions associated with adults' products or with children's products always occurred in the respective age group. Some adverse reactions associated with adults' foaming detergent bath products may have occurred in children and vice versa.

Based on its review of the evidence, however, FDA finds that children are particularly vulnerable to the consumer hazard of primary concern, urogenital injury. There is evidence of an association between urogenital injury and children's products. Although the voluntarily registered industry data were not sufficiently detailed to permit analysis, the agency was able to analyze the complaints that it received directly from consumers about foaming detergent bath products and found that they reported 86 cases of urogenital adverse reactions. Eighty-two percent of those adverse reactions were associated with products intended for use by children. Although it may be that not all of those adverse reactions occurred in children, it is certain that the great majority of them did.

Further, FDA has received a number of reports that were specifically about urogenital injuries to children from foaming detergent bath products. Two pediatricians commented on the proposed stay and reported treating numerous children for urogenital irritation or infection associated with foaming detergent bath products. Thus, seven of the nine physicians who commented reported treating children for urogenital symptoms associated with these products (see 45 FR 55172).

Therefore, FDA is persuaded that, to give appropriate protection to children, § 740.17 should go into effect for all foaming detergent bath products except those intended for use exclusively by adults at the earliest practicable date. Because FDA has determined that 1 year is the appropriate lead time (see 45 FR 55175), the effective date of this regulation will be June 5, 1987.

In the absence of as large a number of urogenital adverse reactions in adults as were observed in children, FDA has decided not to require the caution on products intended for use exclusively by adults. Therefore, FDA is amending § 740.17(b) to make clear that the caution in that section is required on all products except those that are labeled as intended for use exclusively by adults. FDA believes it is appropriate to make these changes at this time because it solicited comment on the issue of the coverage of the regulation in the February 18, 1983, notice.

Consistent with these actions, FDA is continuing the interim stay of the effective date of 21 CFR 740.17 until June 5, 1987, the new effective date of this regulation.

III. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (January 28, 1977; 42 FR 5368). FDA's regulations implementing the National Environmental Policy Act then in effect have been replaced by a rule published in the **Federal Register** of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would be categorically excluded from an environmental assessment and an environmental impact statement under 21 CFR 25.24(a)(11).

IV. Economic Impact

FDA has examined the costs of this regulation and determined that the only significant economic costs are the activities which must be undertaken in order to change packages and labels of foaming detergent bath products. The agency has estimated these costs to be less than $300,000, well under the $100 million per year threshold established by Executive Order 12291 for determining what is a "major" rule. FDA therefore certifies that this is not a major rule as defined by Executive Order 12291, and that it is thus exempt from the requirement for a regulatory impact analysis.

In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has considered the effect that this regulation will have on small entities including small businesses and has determined that it will not place a significantly greater burden on small businesses than on large businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that this regulation will have no significant economic impact on a substantial number of small entities.

List of Subjects in 21 CFR Part 740

Cosmetics, Safety substantiation, Warning statements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Part 740 is amended as follows:

PART 740—COSMETIC PRODUCT WARNING STATEMENTS

1. The authority citation for 21 CFR Part 740 is revised to read as follows:

Authority: Secs. 201(n), 601, 602, 701(a), 52 Stat. 1041, 1054–1055 (21 U.S.C. 321(n), 361, 362, 371(a)); 21 CFR 5.10, 5.11.

2. By revising § 740.17 to read as follows:

§ 740.17 Foaming detergent bath products.

(a) For the purpose of this section, a foaming detergent bath product is any product intended to be added to a bath for the purpose of producing foam that contains a surface-active agent serving as a detergent or foaming ingredient.

(b) The label of foaming detergent bath products within the meaning of paragraph (a) of this section, except for those products that are labeled as intended for use exclusively by adults, shall bear adequate directions for safe use and the following caution:

Caution—Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness, or itching occurs. Consult your physician if irritation persists. Keep out of reach of children.

(c) In the case of products intended for use by children, the phrase "except under adult supervision" may be added at the end of the last sentence in the caution required by paragraph (b) of this section.

Dated: April 28, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 86-12619 Filed 6-4-86; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF STATE

22 CFR Part 51

[Department Regulation 108.849]

Bureau of Consular Affairs; Execution of Passport Application

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending its passport regulations to extend the period of time within which persons previously issued United States passports may apply for new passports without appearing in person before a person authorized by the Secretary of State to administer oaths and accept applications. Additionally, the regulations are being amended to broaden the categories of persons who are eligible to apply for passports without appearing in person.

EFFECTIVE DATE: June 5, 1986.

FOR FURTHER INFORMATION CONTACT: William B. Wharton, Director, Office of Citizenship Appeals and Legal Assistance, Room 5813, Department of State, 2201 C Street, NW, Washington, DC 20520. Telephone (202) 647–6635.

SUPPLEMENTARY INFORMATION: Present regulations allow a U.S. citizen to apply for a new U.S. passport under certain conditions without appearing in person before a person authorized by the Secretary to administer oaths and accept such applications. Personal appearance may not be required when: the most recently issued passport was issued when the citizen was 18 years of age or older; the application is made within eight years from the date on which the most recent passport was issued; and the citizen can present that passport with his or her application for a new passport.

These regulations were promulgated when the maximum validity period for which a passport could be issued was five years. Pub. L. 97–241 (96 Stat. 279 (1983)) extended the period of validity of a passport from five years to ten years. Thus, there was no longer a grace period beyond the passport's expiration date within which a person could apply without appearing before a person authorized by the Secretary of State to administer oaths and accept applications.

The revised regulations will allow persons who have been issued a full validity passport when they were 16 years of age or older to use the "mail-in" procedure to obtain a new passport within twelve years after the date on which the expired passport was issued.

Consideration has been given to the need to balance the requirements for identification and the convenience to the traveling citizen. The Federal Advisory Committee on False Identification (FACFI) evaluated various identification systems and processes. The conclusions and recommendations of FACFI's Report of November 1976 were taken into account at the time the Department was considering implementation of the 10 year passport legislation. The regulations permitting the use of this "mail-in" procedure allows applicants a grace period within which to apply without impairing the reliability of the passport as an identity document. In addition, extending the "mail-in" procedures to minors whose previous passports were issued when they were 16 years of age or older will extend the benefits of this procedure to an increased number of people.

Since this amendment to the regulations is being made to bring them into conformity with the legislation referred to above, and extends a benefit to passport applicants, the Department has determined that the public notice requirement of the Administrative Procedure Act (APA), 5 U.S.C. 553, as amended, may be dispensed with because it is unnecessary. 5 U.S.C. 553(b)(B).

The Department has also determined that this regulation will not impose unnecessary burdens on individuals or on the economy and, therefore, is not significant for the purpose of Executive Order 12044.

List of Subjects in 22 CFR Part 51

Administrative practice and procedure, Passports and visas.

PART 51—[AMENDED]

22 CFR Part 51 is amended as follows:

1. The authority citation for Part 51 is revised to read as follows:

Authority: Sec. 1, 44 Stat. 887; sec. 1, 41 Stat. 750; sec. 2, 44 Stat. 887; sec. 4, 63 Stat. 111, as amended (22 U.S.C. 211a, 214, 217a, 2658); E.O. 11295, 36 FR 10603; 3 CFR 1966–70 Comp. p. 507.

2. In § 51.21, paragraphs (a), (c), and (d) are revised to read as follows:

§ 51.21 Execution of passport application.

(a) *First time applicants or persons who have not been issued a passport within the past twelve years.* A person who has never been issued a passport in his or her own name, or who has not been issued a passport in his or her own name within 12 years of the date of a new application, shall appear in person before a person authorized by the Secretary to give oaths, verify the application by oath or affirmation before that authorized person, provide two recent photographs, and pay the established fees.

* * * * *

(c) *Persons in the United States who have previously been issued a full validity passport.* A person in the United States who has been issued a passport in his or her own name may obtain a new passport by filling out and mailing a specially prescribed application together with his or her previous passport, two recent photographs, and the established fee to the nearest U.S. Passport Agency provided:

(1) The most recently issued previous passport was issued when the applicant was 16 years of age or older;

(2) The application is made not more than 12 years following the issue date of the previous passport;

(3) The most recently issued previous passport is submitted with the new application.

(d) *Persons outside of the United States who have previously been issued a full validity passport.* In a foreign country in which a U.S. consular district has been designated by the Secretary to receive such passport applications, a person who has been issued a passport in his or her own name may obtain a new passport by filling out a specially prescribed application and sending it (by mail or as prescribed by the Secretary), together with his or her previous passport, two recent photographs, and the established fee to the consular office in the consular district in which he or she is present, provided:

(1) The most recently issued passport was issued when the applicant was 16 years of age or older;

(2) The application is made not more than 12 years following the issue date of the previous passport;

(3) The most recently issued previous passport is submitted with the new application.

For the Secretary of State.

Dated: May 22, 1986.

Joan M. Clark,

Assistant Secretary, Bureau of Consular Affairs.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Part 15

[Docket No. R-86-1236; FR-2014]

Disclosure of Profit and Loss Information to Potential Purchasers of HUD-Held Mortgages

AGENCY: Office of the Secretary, HUD.

ACTION: Interim rule.

SUMMARY: This interim rule revises the regulations at 24 CFR Part 15 governing disclosure of departmental records. This rule clarifies the records that may be withheld from inspection or copying under 24 CFR 15.21(a)(4), i.e., "trade secrets and commercial or financial information", and provides for the disclosure of information on Form HUD-92410, Statement of Profit and Loss, to prospective eligible bidders (as defined in the auction announcement) on mortgages offered in the Department's multifamily mortgage auctions. HUD has determined that the disclosure to potential bidders of information in the Profit and Loss Statement is necessary for the successful conduct of these mortgage sales.

DATES: Effective date: July 21, 1986.

Comment due date: August 4, 1986.

Mortgagors of projects for which HUD holds the mortgage may request that HUD not release Form HUD-92410 in connection with any mortgage auctions conducted before the effective date of the final rule in this rulemaking. These requests must be addressed in writing to: Marvin Hillman, Director, Multifamily Property Disposition Division, Office of Multifamily Housing Management, Department of Housing and Urban Development, Room 6272, 451 Seventh Street SW., Washington, DC 20410. The Department must receive these request by August 4, 1986. Unless an affected mortgagor forwards its request to HUD within that deadline, HUD may release Form HUD-92410 to prospective eligible bidders subject to the conditions in this interim rule.

ADDRESS: Interested parties are invited to submit comments to the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, Room 10276, 451 Seventh Street SW., Washington, DC 20410. Communications should refer to the above docket number and title. A copy of each communication will be available for public inspection during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Marvin Hillman, Director, Multifamily Property Disposition Division, Office of Multifamily Housing Management, Department of Housing and Urban Development, Room 6272, 451 Seventh Street SW., Washington, DC 20410. Telephone (202) 755-7343. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

I. Background

HUD mortgage auctions involve two types of mortgages:

(2) *Assigned mortgages:* These mortgages secure loans that were originally made by the lender and insured by HUD under the National Housing Act. Lenders have assigned these mortgages to HUD after a default. The Department pays insurance benefits to the lender and thus becomes the new mortgagee.

(2) *Purchase money mortgages.* These mortgages were taken back by the Department in conjunction with the sale of a HUD-owned property. HUD acquired the property by foreclosing on an assigned mortgage, taking a deed-in-lieu-of-foreclosure, or by accepting conveyance of title from the insured lender.

The Department has determined that the disclosure of information on Form HUD-92410, Statement of Profit and Loss, to prospective eligible bidders (as defined in the auction announcement) on mortgage offered in HUD multifamily mortgage auctions is necessary for the successful conduct of future auctions. (For purposes of this interim rule, "auction" includes any mortgage sale procedure where oral or written bids are submitted to HUD or its authorized agent.) Such disclosure is important because eligible bidders have advised HUD that they need access to profit and loss information in order to make an informed decision about whether to bid and how much to bid on certain mortgages. Disclosure of this type of financial information concerning the property securing the mortgage is vital to enhancing the level of participation in and the success of HUD's mortgage auctions. The form includes specific income sources and amounts and project expense categories. (A listing of the data entry categories included in Form HUD-92410 is published as an appendix to this interim rule, so that commenters will be fully apprised of the kinds of data proposed to be made available in connection with mortgage auctions.)

The availability of this information to qualified bidders is particularly important because of the reaction of bidders during recent auctions. In the two 1984 auctions, when information from Form HUD-92410 was not released to potential bidders, 315 mortgages were offered, but only 47 were sold—a 15 percent sales rate. In five previous auctions during 1982-83, when such information was released to potential bidders, 1,372 mortgages were offered for sale, and 400 (20 percent) were sold. Similarly, the ratio of mortgages bids (i.e., bids received from a bidder other than the mortgagor) received to mortgages offered has significantly decreased in the two 1984 auctions. In those two auctions, a total of 57 morgtgagee bids was received, (a ratio of bids to mortgages offered of approximately 1:5), as contrasted with 820 mortgagee bids in the previous four auctions (a ratio of approximately 2:3).

This substantial drop in interest on the part of potential mortgage purchasers is no doubt attributable in part to HUD's February 10, 1984 memorandum announcing discontinuation of FHA insurance on auction mortgages. However, it is also