made for reasons of maintaining the continuity of service of the reporting entity's bulk electric power supply system. (ACO shall be notified as soon as practicable, but no later than 24 hours after the issuance of such a request.)

(b) Any intentional reduction of system voltage by 3 percent or greater for reasons of maintaining the continuity of service of the reporting entity's bulk electric power supply system. (ACO shall be notified as soon as practicable, but no later than 24 hours after the initiation of the action.)

(c) Any load shedding action that results in the reduction of over 100 megawatts (MW) of firm customer load for reasons of maintaining the continuity of service of the reporting entity's bulk electric power supply system. The routine use of load control equipment that reduces firm customer load is not considered to be a reportable action. (ACO shall be notified within three hours after such action is taken if practicable, or as soon thereafter as practicable.)

(d) Any electric power supply equipment or facility failure or other event that, in the judgment of the reporting entity, constitutes a hazard to the current or prospective adequacy and/or reliability of the reporting entity's bulk electric power supply system. (ACO shall be notified as soon as practicable; however reports are expected within one business day after such determination.) Examples of situations which *may* be reportable under this provision *could* be ones which:

(1) Cause the operating area to be dependent upon neighboring utilities for large quantities of unscheduled electricity deliveries to supply the operating area's loads for longer than three consecutive hours;

(2) Cause a significant increase in the use of a fuel for generating equipment, such that replacement of this fuel may be a problem;

(3) Are caused by a suspected act of physical sabotage.

(e) Any outage that extends for greater than 15 minutes and affects firm loads totaling over 100 MW, or more than 50 percent of the total load being supplied by the reporting entity's system immediately prior to the incident, whichever is less. However, utilities with a peak load in the prior year of over 3000 MW are only to report those losses of service to firm loads totaling over 200 MW for greater than 15 minutes. (ACO shall be notified as soon as practicable without unduly interfering with service restoration and, in any event, within three hours after the beginning of the interruption.)

(f) Any significant incident on an electric utility system which results in a continuous outage of three hours or longer to over 50,000 customers (meters, delivery points) or more than one half of the reporting entity's total customers, whichever is less. (ACO shall be notified within 24 hours of the occurrence if practicable, or as soon thereafter as practicable.)

(OMB Control No. 1903–0045)

§ 205.352 Information to be reported.

The power supply data shall be supplied to the ACO in accordance with the current DOE pamphlet on reporting procedures. The initial report should include the utility name; the area affected; the time of occurrence of the initiating event; the duration or an estimate of the likely duration; an estimate of the number of customers and amount of load involved; and whether any known critical services such as hospitals, military installations, pumping stations, or air traffic control systems, were or are interrupted. To the extent known or suspected, the report shall include a description of the events initiating the disturbance. The DOE may require further clarification during or after restoration of service.

§ 205.353 Fuel emergencies.

The ACO shall be notified whenever a utility or other subject entity determines that a fuel supply emergency exists or is projected to occur. A fuel supply emergency exists when supplies of fuels or hydroelectric storage for generation are at a level or projected to be at a level which would threaten the reliability or adequacy of electric service. The following factors should be taken into account to determine whether a fuel emergency exists: (a) fuel stocks or hydro storage levels are 50 percent or less of normal for that particular time of the year and; (b) a continued downward trend in fuel stocks or hydro storage levels is projected. (ACO shall be notified as soon as practicable, but no later than three days after the determination is made.)

§ 205.354 Special investigations and reports.

If directed by the Director, Office of Energy Emergency Operations in writing and noticed in the Federal Register, a utility or other subject entity experiencing a condition described in § 205.351 above shall submit a full report of the technical circumstances surrounding the power system disturbance, including the restoration procedures utilized. The report shall be filed at such time as may be directed by the Director, Office of Energy Emergency Operations.

§ 205.355 [Removed]

[FR Doc. 83-3296 Filed 2-7-83; 8:45 am]
BILLING CODE 6450-01-M

FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Docket No. R-0451]

Regulation D; Reserve Requirements of Depository Institutions; Ineligible Bankers' Acceptances

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Proposed rulemaking.

SUMMARY: Under the Board's current Regulation D—Reserve Requirements of Depository Institutions (12 CFR Part 204), a bankers' acceptance ("BA") that does not meet the criteria of section 13 of the Federal Reserve Act ("ineligible BA") is regarded as a reservable deposit only if it is created, discounted, and sold by the *same* depository institution. In order to avoid reserve requirements, some banks have recently entered into arrangements with brokers and other third parties that provide for the issuance of an ineligible BA by the bank and the subsequent discount and/or resale by a third party. To prevent the use of this device as a means of avoiding reserve requirements, the Board proposes to amend Regulation D such that the creation of an ineligible BA results in a reservable liability regardless of whether the depository institution that creates the BA subsequently discounts and/or sells it.

DATE: Comments must be received by March 18, 1983.

ADDRESS: Interested parties are invited to submit written data, views, or arguments concerning the proposed rule to William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, D.C. 20551, or such comments may be delivered to room B-2223 between 8:45 a.m. and 5:15 p.m. Comments may be inspected in room B-1122 between 8:45 a.m. and 5:15 p.m., except as provided in § 261.6(a) of the Board's Rules Regarding Availability of Information (12 CFR 261.6(a)).

FOR FURTHER INFORMATION CONTACT: Gilbert T. Schwartz, Associate General Counsel (202/452-3625); Paul S. Pilecki,

Senior Attorney (202/452-3281); or Robert G. Ballen, Attorney (202/452-3265), Legal Division, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

SUPPLEMENTARY INFORMATION: Section 19(a) of the Federal Reserve Act authorizes the Board to determine what types of obligations are reservable deposits (12 U.S.C. 461(a)). In addition, section 19(a) grants the Board authority to prescribe regulations necessary to prevent evasions of reserve requirements.

Regulation D currently regards an ineligible BA as a reservable deposit only if it is created, discounted, and sold by the same depository institution. Some banks have recently entered into agented BA arrangements with brokers and other third parties that provide for the issuance of an ineligible BA by the bank and the subsequent discount and/or resale by the third party. Since the bank issuing the BA did not discount and resell the acceptance, currently it is not required to maintain reserves against the BA. Similarly, the third party depository institution that discounts and/or resells the BA pursuant to such an arrangement would not be subject to reserve requirements on the transaction since it did not issue the BA. The Board believes that these arrangements serve only as a device to avoid reserve requirements under Regulation D. In order to prevent reserve requirement evasion, the Board proposes to amend Regulation D such that the creation of an ineligible BA results in a reservable deposit regardless of whether the depository institution that creates the BA subsequently discounts and/or sells it. The Board notes that where the party discounting or selling the BA is not the same institution that created the BA, it is in many cases difficult, if not impossible, to determine whether the discount and sale of the BA have occurred pursuant to a prearranged agented BA transaction. Commenters may also wish to address whether reserve requirements should be applied *only* to agented BA transactions and how such agented arrangements may be identified—in addition to comments on other aspects of the proposal.

It should be noted that under the proposal reserve requirements would not apply to an ineligible BA that the issuing institution itself discounts and holds since under current practices, such acceptances are not regarded as acceptances outstanding. Further, due to equity considerations, the Board proposes that this amendment not apply to outstanding ineligible BAs that were created prior to the announcement of the proposed amendment. Depository institutions would be on notice that under the proposal all ineligible BAs created after the date of the announcement would be subject to reserve requirements even if the creating institution did not itself discount and sell the acceptance. Comments on this proposed amendment must be received by March 18, 1983.

The impact of this proposal on small entities has been considered in accordance with section 603 of the Regulatory Flexibility Act (Pub. L. 96-354; 5 U.S.C. 603). Section 411 of the Garn-St Germain Depository Institutions Act of 1982 (Pub. L. 97-320; 96 Stat. 1520) provides for an exemption from reserve requirements for the first $2.1 million in reservable liabilities at all depository institutions. The Board believes that its proposed action would not add any reserve requirement burden to small depository institutions that have zero reserve requirements as a result of section 411 of the Garn-St Germain Act. In addition, small entities typically do not issue ineligible BAs. No new recordkeeping or reporting requirements will be imposed as result of this action.

List of Subjects in 12 CFR Part 204

Banks, banking, Currency, Federal Reserve System, Penalties, Reporting and recordkeeping requirements.

PART 204—[AMENDED]

Pursuant to its authority under section 19 (a) of the Federal Reserve Act (12 U.S.C. 461(a)), the Board proposes to amend § 204.2 of Regulation D (12 CFR Part 204) by redesignation existing paragraph (a)(1)(vii) as (a)(1)(viii); and by amending newly redesignated (a)(1)(viii) by removing the words "banker's acceptance,", by adding the word "or" at the end of subparagraph (C), by changing the semi-colon at the end of subparagraph (D) to a period, by removing the word "or" at the end of subparagraph (D), and by removing subparagraph (E) and by adding a new paragraph (a)(1)(vii) to read as follows:

§ 204.2 Definitions.

* * * * *

(a)(1) * * *

(vii) any liability of a depository institution that arises from the creation after January 31, 1983, of a bankers' acceptance that is not of the type describe in paragraph 7 of section 13 of the Federal Reserve Act (12 U.S.C. 372); or

* * * * *

By order of the Board of Governors, Feburary 1, 1983.

William W. Wiles,

Secretary of the Board.

[FR Doc. 83-3210 Filed 2-7-83; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172, 182, and 184

[Docket No. 78N-0349]

Certain Glycerides; Proposed Affirmation of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to affirm that mono- and diglycerides, diacetyl tartaric acid esters of nomo- and diglycerides, monosodium phosphate derivatives of mono- and diglycerides, glyceryl monostearate, glyceryl monooleate, triacetin, and tributyrin are generally recognized as safe (GRAS) as direct human food ingredients. The agency is also proposing to remove glyceryl monooleate from the list of food additives. The safety of these ingredients has been evaluated under a comprehensive safety review conducted by the agency. A proposal to affirm glycerin as GRAS appears elsewhere in this issue of the **Federal Register**.

DATE: Comments by April 11, 1983.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Susan Thompson, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive review of human food ingredients classified as GRAS or subject to a prior sanction. The agency has issued several notices and proposals (see the **Federal Register** of July 26, 1973 (38 FR 20040)) initiating this review, under which the safety of mono- and diglycerides, diacetyl tartaric acid esters of mono- and diglycerides, monosodium phosphate derivatives of mono- and diglycerides, glyceryl monostearate, glyceryl monooleate, triacetin, and tributyrin has been evaluated. In accordance with the provisions of § 170.35 (21 CFR 170.35),

the agency proposes to affirm the GRAS status of these ingredients. The agency is proposing no action on the prior-sanctioned status of sodium sulfoacetate derivatives of mono- and diglycerides, which are currently listed in the standards of identity for margarine.

In its report, the Select Committee on GRAS Substances (the Select Committee) also evaluated the safety of acetooleins, acetostearings, glyceryl lactopalmitate, glyceryl lactooleate, monoglyceride citrate, and oxystearin. However, these substances are food additives regulated under § 172.828 (acetooleins, acetostearins), § 172.852 (glyceryl lactopalmitate, glyceryl lactooleate), § 172.832 (monoglyceride citrate), and § 172.818 (oxystearin) (21 CFR 172.828, 172.852, 172.832, and 172.818). The agency is not addressing the safety of these additives at this time but will consider the information evaluated by the Select Committee in an upcoming review of the safety of food additives.

Mono- and diglycerides were first used in foods in the United States in 1911. They are composed of esters of glycerin in which one or two of the hydroxy groups of glycerin are esterified by fatty acids. The most prevalent fatty acids include lauric, linoleic, myristic, oleic, palmitic, and stearic acid. Mono- and diglycerides do not occur naturally in appreciable quantities, except in fats that have undergone partial hydrolysis. These glycerides are manufactured by the glycerolysis of edible fats and oils or by the esterification of glycerin with edible fatty acids that meet the requirements of § 172.860 (21 CFR 172.860), with or without molecular distillation of the products.

Mono- and diglycerides from glycerolysis of edible fats or oils were listed as GRAS as emulsifying agents in a regulation published in the **Federal Register** of November 20, 1959 (24 FR 9368). Subsequently, this listing was replaced by the listing of mono- and diglycerides of edible fats or oils, or of edible fat-forming fatty acids, as GRAS as emulsifying agents in a regulation published in the **Federal Register** of December 2, 1964 (29 FR 16079). These substances are currently listed as GRAS for this use in § 182.4505 (21 CFR 182.4505). Mono- and diglycerides from glycerolysis of edible fats and oils were listed as GRAS as substances migrating to food from paper and paperboard products in a regulation published in the **Federal Register** of June 17, 1961 (26 FR 5421) and are currently listed as GRAS for this use in § 182.90 (21 CFR 182.90).

Mono- and diglycerides have a U.S. Department of Agriculture (USDA) prior sanction under the Meat Inspection Act for use as emulsifiers in lard, shortening, and oleomargarine. Mono- and diglycerides of fat-forming fatty acids are listed as optional ingredients in the following food standards of identity: *Bread, rolls, and buns* (21 CFR 136.110); *Sweet chocolate* (21 CFR 163.123); and *Milk chocolate* (21 CFR 163.130). Mono- and diglycerides of fatty acids are listed as optional ingredients in the food standard in *Margarine* (21 CFR 166.110).

Glycerides, di- and monoester, are listed as food additives in 21 CFR 175.105 as components of adhesives. Mono- and diglycerides are listed as food additives in 21 CFR 176.210 as components of defoaming agents used in the manufacture of paper and paperboard.

Glyceryl monooleate is the monoester of glycerin and oleic acid. This monoglyceride is prepared by esterification of oleic acid with glycerin. FDA has stated in opinion letters that glyceryl monooleate is GRAS for use as an emulsifier in color mixtures for margarine (1958 letter) and as a vitamin oil emulsifier for use in fluid milk (1962 letter). Glyceryl monooleate is listed, under the name of glycerol monooleate, in § 181.27 (21 CFR 181.27) as a prior-sanctioned food ingredient when used as a plasticizer in food-packaging material. Glyceryl monooleate is listed in § 172.515 (21 CFR 172.515) as a synthetic flavoring substance and adjuvant. It is also listed in 21 CFR 175.300(b)(3)(xxiv) as a plasticizer of resinous and polymeric coatings and in 21 CFR 175.320(b)(3)(ii), under the name of glycerol monooleate, as a plasticizer in resinous and polymeric coatings for polyolefin films.

Glyceryl monostearate or monostearin is the monoester of glycerin and stearic acid. The commercial product is a mixture of variable proportions of glyceryl monostearate and glyceryl monopalmitate. Glyceryl monostearate is prepared by glycerolysis of certain edible fats and oils or by esterification of stearic acid with glycerin. Glycerol monostearate was listed as GRAS as a miscellaneous substance in a regulation published in the **Federal Register** of November 20, 1959 (24 FR 9368). Subsequently, glyceryl monostearate was reclassified as GRAS as a miscellaneous and general purpose food additive in a regulation published in the **Federal Register** of January 31, 1961 (26 FR 938), and reclassified and recodified as a multiple purpose GRAS food substance in the **Federal Register** of March 15, 1977 (42 FR 14640). Currently, glyceryl monostearate is listed as GRAS as a multiple purpose GRAS food substance in § 182.1324 (21 CFR 182.1324). Glyceryl monostearate is listed as an optional ingredient in the standard of identity for macaroni products (21 CFR 139.110) and for noodle products (21 CFR 139.150). Glyceryl monostearate is also listed in 21 CFR 175.210 as an indirect food additive for use as a component of acrylate ester copolymer coatings, in 21 CFR 175.300(b)(3)(xxvii) for use as a surface lubricant in resinous and polymeric coatings, and in 21 CFR 176.200 for use as a component of defoaming agents used in coatings.

Diacetyl tartaric acid esters of mono- and diglycerides are composed of mixed esters of glycerin, tartaric acid, and fatty acids. The commercial product is prepared by the reaction of diacetyl tartaric acid anhydride with mono- and diglycerides made from edible fats, oils, and fatty acids. Diacetyl tartaric acid esters of mono- and digylcerides from glycerolysis of edible fats or oils were listed as GRAS as emulsifying agents in a regulation published in the **Federal Register** of November 20, 1959 (24 FR 9268). Subsequently, the listing was replaced by the listing of diacetyl tartaric acid esters of mono- and digylcerides of edible fats or oils, or edible fat-forming fatty acids, as GRAS as emulsifying agents in a regulation published in the **Federal Register** of December 2, 1964 (29 FR 16079). These substances are currently listed as GRAS for this use in § 182.4101 (21 CFR 182.4101). These esters also have a USDA prior sanction for emulsifying rendered animal fat or a combination of rendered amimal fat with vegetable fat, in an amount sufficient for the purpose. Diacetyl tartaric acid esters of mono- and diglycerides of fat-forming fatty acids are listed as optional ingredients in the standards of identity for bread, rolls, and buns (21 CFR 136.110).

Monosodium phosphate derivatives of mono- and diglycrides are composed of a mixture of glyceride derivatives formed by reacting mono- and diglycerides with phosphorus pentoxide and then neutralizing the product with sodium carbonate. Monosodium phosphate derivatives of mono- and diglycerides from the glycerolysis of edible fats or oils were listed as GRAS as emulsifying agents in a regulation published in the **Federal Register** of November 20, 1959 (24 FR 9368). Subsequently, this listing was replaced by the listing of monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids, as GRAS as emulsifying agents in a regulation published in the **Federal Register** of December 2, 1964 (29 FR 16079). These substances are currently listed as GRAS for this use in

§ 182.4521 (21 CFR 182.4521). Monosodium phosphate derivatives of mono- and diglycerides of fat-forming fatty acids are listed as optional emulsifying agents in the standards of identity for sweet chocolate (21 CFR 163.123) and for milk chocolate (21 CFR 163.13)

Triacetin, also referred to as 1, 2, 3,-propanetriol or glyceryl triacetate, is the triester of glycerin and acetic acid. This ester is prepared by acetylation of glycerin or by the reaction of oxygen with the liquid-phase of mixture of allyl acetate and acetic acid, using bromide as a catalyst. Triacetin (glyceryl triacetate) was listed as GRAS as a miscellaneous substance in a regulation published in the **Federal Register** of November 20, 1959 (24 FR 9368). Subsequently, triacetin (glyceryl triacetate) was reclassified as a miscellaneous and general purpose food additive in a regulation published in the **Federal Register** of January 31, 1961 (26 FR 938). Triacetin was reclassified and recodified as a multiple purpose GRAS food substance in a regulation published in the **Federal Register** of March 15, 1977 (42 FR 14640), and is currently listed a GRAS for this use in § 182.1901 (21 CFR 182.1901). It is also listed in § 181.27 as a prior-sanctioned food ingredient when used as a plasticizer in food-packaging material. Furthermore, triacetin is regulated as a food additive under the name "glyceryl triacetate" in 21 CFR 175.300(b)(3)(xxiv) as a plasticizer in resinous and polymeric coatings and under the name "glycerol triacetate" in 21 CFR 175.320(b)(3)(ii) as a plasticizer in resinous and polymeric coatings for polyolefin films.

Tributyrin, also referred to as glyceryl tributyrate, is the triester of glycerin and butyric acid. It is prepared by esterification of glycerin with excess butyric acid. It was listed as GRAS under the designation "glycerol (glyceryl) tributyrate (tributyrin, butyrin)" for use as a synthetic flavoring substance and adjuvant is a regulation published in the **Federal Register** of May 9, 1961 (26 FR 3991), and currently is listed a GRAS in § 182.60 (21 CFR 182.60) for this use.

In 1971, the National Academy of Sciences/National Research Council (NAS/NRC) surveyed a representative cross-section of food manufacturers to determine the specific foods in which GRAS substances were used and the levels of usage. The survey revealed that mono- and diglycerides are used in most of the food categories listed in 21 CFR 170.3(n) as dough strengtheners, emulsifiers and emulsifier salts, flavoring agents and adjuvants, lubricants and release agents, solvents and vehicles, stabilizers and thickeners, surface-active agents, surface-finishing agents, and texturizers. The survey also reported that glyceryl monostearate, which was listed individually, is used as a firming agent and as processing aid, as well as for most of the technical effects reported for mono- and diglycerides. The survey also reported that glyceryl monooleate is used as a flavoring agent and as a solvent and vehicle in baked goods, nonalcoholic beverages, and meat products.

The survey also reported the use of diacetyl tartaric acid esters of mono- and diglycerides as emulsifiers in baked goods, confections and frostings, and dairy product analogs and as flavoring substances in fats and oils. The survey reported the use of monosodium phosphate derivatives of mono- and diglycerides as emulsifiers and as surface-active agents in dairy product analogs. In addition, correspondence to FDA reported the use of these derivatives as lubricants and as release agents. The survey reported the use of triacetin as a flavoring agent, humectant, solvent or vehicle in alcoholic beverages; baked goods; chewing gums; confections and frostings; frozen dairy desserts and mixes; gelatins, puddings, and fillings; hard candy; nonalcoholic beverages; and soft candy. Finally, the survey reported the use of tributyrin as a flavoring agent in alcoholic beverages; baked goods; fats and oils; frozen dairy desserts and mixes; gelatins, puddings, and fillings; nonalcoholic beverages; and soft candy.

NAS/NRC combined this manufacturing information with information on consumer consumption of food to obtain an estimate of consumer exposure to these ingredients. FDA estimates from the NAS/NRC survey that the total amount of these ingredients used in 1970 was 132 million pounds. FDA further estimates that the total amounts of the various glycerides used in 1970 were as follows: mono- and diglycerides, 121 million pounds, 1.6 times that used in 1960; glyceryl monostearate, 10.3 million pounds, 5.7 times that used in 1960; diacetyl tartaric esters of mono- and diglycerides, 704,000 pounds, 1,007 times that used in 1960; triacetin (glyceryl triacetate), 61,600 pounds, 3.5 times that used in 1960; monosodium phosphate derivatives of mono- and diglycerides, 44,000 pounds; tributyrin, 1,000 pounds; and glyceryl monooleate, 44 pounds.

Glycerin and glycerides have been the subjects of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavorial effects, (12) detection, and (13) processing. A total of 1,817 abstracts on glycerin and glycerides was reviewed, and 103 particularly pertinent reports from the literature survey have been summarized in a scientific literature review.

Information from the scientific literature review has been summarized in a report to FDA by the Select Committee, which is composed of qualified scientists chosen by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (FASEB). The members of the Select Committee have evaluated all available safety information on glycerides.[1] In the Select Committee's opinion:

Although mono-and diglycerides of edible fat-forming fatty acids are found naturally, those that are used as food additives are usually prepared synthetically. Mono-, di- and triglycerides are metabolized by the same mechanisms. The biological effects of glycerides are either those of the entire molecule or of the metabolic products, fatty acids and glycerin. Triglyceride fats are a major source of calories in the diet of many people. Mono- and diglycerides are minor components of natural fats. They are intermediate metabolic products of ingested triglycerides. There is no evidence that the mono- and diglycerides of edible fat-forming fatty acids behave differently from triglycerides upon ingestion.

There is evidence that ingestion of excesses of saturated fats and cholesterol promotes arteriosclerosis and cardiovascular disease. Continuation of research in this area may refine relationships of the various fatty acids to the point where harmfulness may become an impelling consideration. However, because of a reasonable estimate of the consumption of all added mono- and diglycerides is of the order of 1 to 10 g per person per day, only a fraction of which contains saturated fatty acids, it can hardly be concluded that they make a sufficient contribution to any hazard associated with

[1] "Evaluation of the Health Aspects of Glycerin and Glycerides as Food Ingredients," Life Sciences Research Office, Federation of America Societies for Experimental Biology, 1975, pp. 19–22. In the past, the agency presented verbatim the Select Committee's discussion of the biological data it reviewed. However, because the Select Committee's report is available at the Dockets Management Branch and from the National Technical Information Service, and because it represents a significant savings to the agency in publication costs, FDA has decided to discontinue presenting the discussion in the preambles to proposals that affirm GRAS status in accordance with current good manufacturing practice.

normal ingestion of saturated fatty acids in fatty foods to justify limitation of the level of their current use.

The diacetyl tartaric acid esters of mixed mono- and diglycerides have been found to be without toxic effects in long-term feeding experiments with rats and dogs at levels that were orders of magnitude greater than those to which consumers are exposed.

Triacetin and two types of acetooleins have been found to be without toxic effects in long-term feeding tests in rats at levels that were several orders of magnitude greater than those to which consumers are exposed.

* * * [2]

The Select Committee concludes that:

1. There is no evidence in the available information on mono- and diglycerides of fat-forming fatty acids, diacetyl tartaric acid esters of mono- and diglycerides, and triacetin that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or that may reasonably be expected in the future.

2. There are inadequate data to evaluate the safety of monosodium phosphate derivatives of mono- and diglycerides.

FDA has undertaken its own evaluation of all available information on glycerides, including mutagenic evaluations of glyceryl monostearate and triacetin that were not availbale to the Select Committee.

1. The agency concurs with the Select Committee's conclusion for mono- and diglycerides of fat-forming fatty acids, diacetyl tartaric acid esters of mono- and diglycerides of fat-forming fatty acids, and triacetin. Therefore, the agency concludes that no change in their GRAS status is justified and proposes to affirm the GRAS status of uses of these substances in food.

The Select Committee reached a single conclusion regarding the safety of mono- and diglycerides of edible fat-forming fatty acids. However, it is clear from the background information, the biological studies section, and the opinion statement in the report [3] that this one conclusion by the Select Committee covers serveral ingredients that FDA had previously considered as separate GRAS ingredients. These include mono- and diglycerides of edible fats and oils or of edible fat-forming acids, glyceryl monostearate, and glyceryl monooleate. These ingredients are toxicologically equivalent and are all prepared by the same manufacturing methods. The differences in these ingredients reflect differences in the fatty acid content of the starting materials and minor variations in the reaction conditions. However, these ingredients have very different uses in food. Clyceryl monostearate has a separate listing as a general purpose GRAS food ingredient and, as reported in the NAS/NRC survey, has a wide variety of uses in food including use as an emulsifier. Mono- and diglycerides are currently listed as GRAS as emulsifiers and, as reported in the NAS/NRC survey, are used in food primarily for that prupose. Glyceryl monooleate is regulated for flavoring use as a food additive and, as reported in the NAS/NRC survey, its use in food is limited to a flavor or flavor vehicle. Therefore, in response to the Select Committee's conclusion for mono- and diglycerides of edible fat-forming fatty acids, the agency is proposing to affirm as GRAS the use of three ingredients in food, mono- and diglycerides, glyceryl monostearate, and glyceryl monooleate.

2. In proposing these regulations, the agency has tentatively decided to change the way in which it refers to mono- and diglycerides and their derivatives. In the past, for mono- and diglycerides, FDA included in the name of the ingredient the identity of the starting material (mono- and diglycerides from edible fats or oils or edible fat-forming acids). The resulting name "mono- and diglycerides of edible fats or oils or edible fat-forming acids" was cumbersome, but FDA considered such a name necessary to identify adequately the ingredient that the agency considered to be GRAS. However, FDA now believes that information on the identity of the ingredient is more appropriately included in paragraph (a) of the GRAS affirmation regulation than in the name of the ingredient. Therefore, FDA has tentatively decided to refer to these mixtures as "mono- and diglycerides." The agency is also modifying in paragraph (a) of this GRAS affirmation regulation, the description of the source materials used to produce mono- and digylcerides. The restriction on source materials included in the previous listing was intended to exclude the use of improper sources, such as tall oil, castor oil, or fat from animals classified by the U.S. Department of Agriculture as 4–D, i.e., dead, dying, diseased, or down. However, the agency had no intention to exclude the use of unrefined animal and vegetable fats as production starting materials. Therefore, the agency is describing the source materials for production of mono- and digylcerides and their derivatives as fats and oils or fat-forming acids from edible sources.

3. FDA is proposing to remove glyceryl monooleate from the agency's food additive regulations as a food flavor (21 CFR 172.515) and to affirm it as GRAS in Part 184 (21 CFR Part 184). This proposal is consistent with previous FDA actions during the GRAS review of food flavoring ingredients. The basis for this proposal is the Select Committee's conclusion that mono- and diglycerides of edible fat-forming fatty acids are safe for use in food at current or reasonably expected future levels. This finding evidences the general recognition of the safety of this ingredient among food scientists. Therefore, because the Select Committee included glyceryl monooleate in this group of substances, its conclusion for mono- and diglycerides of edible fat-forming fatty acids applies to glyceryl monooleate. Furthermore, in prior opinion letters the agency has stated that certain food uses of glyceryl monooleate are GRAS. Therefore, the agency believes that glyceryl monooleate is properly included among the ingredients listed in Part 184.

The agency is proposing not to affirm the use of glyceryl monooleate as an emulsifier in color mixtures for margarine or as a vitamin oil emulsifier for use in fluid milk. Even though the agency has stated in opinion letters that these uses of glyceryl monooleate were GRAS, they were not reported during the 1971 NAS/NRC survey. The agency will consider including these uses in the final regulation if information confirming the current use of glyceryl monooleate for these purposes is submitted as comments on this proposal.

4. The agency acknowledges the absence of biological data specifically relating to monosodium phosphate derivatives of mono- and diglycerides. However, the agency has undertaken its own review of these substances, including an evaluation of any potential impurities resulting from the manufacturing process and of the safety of the hydrolysis products that are formed following ingestion (mono- and diglycerides and phosphate derivatives). The Select Committee addressed the safety of phosphoric acid, sodium phosphate, and other phosphates in a separate report and concluded that they were safe for use in food at present and future anticipated levels of use.[4] The agency concurs with the conclusions of the Select Committee regarding the safety of phosphates and mono- and diglycerides. The agency further concludes that there are no potential safety hazards resulting from the

[3] *Ibid.*, p. 23.

[3] *Ibid.*, pp. 12, 19, 23.

[4] "Evaluation of the Health Aspects of Phosphates as Food Ingredients," Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1975, p. 26.

manufacturing process, and that the data supporting the safety of mono- and diglycerides and of the phosphates are sufficient to establish the safety of the use of monosodium phosphate derivatives of mono- and diglycerides in food. Thus, FDA believes that no change in the GRAS status of this ingredient is justified. Consequently, the agency is proposing to affirm the use of this ingredient in food as GRAS under conditions of current good manufacturing practice and to take no action on the listings of this substance in the food standards.

5. The safety of tributyrin was not considered in the Select Committee's report on glycerin and glycerides. However, because this substance is listed as GRAS in § 182.60 (21 CFR 182.60), FDA initiated its own review of the available safety data on tributyrin. In the one study in the literature on carcinogenicity (Ref. 1), tributyrin was found not to be a carcinogen in the A/He mouse pulmonary systems. Apparently, no other carcinogenicity studies have been done. In short-term and acute toxicity tests (Ref. 2), ingestion of high levels of tributyrin (15 to 25 percent) for 3 to 35 weeks was associated with gastric lesions in rats. However, the authors felt that these lesions could have been partially the result of the low nutritive value of the test diet. Tributyrin has a relatively high LD_{50} (320 milligrams per kilogram body weight i.v.) in the mouse (Ref. 3). In metabolism and absorption studies, feeding tributyrin to rats was observed to have no effect upon lymphatic transport of endogenous cholesterol from the intestine (Ref. 4). Tributyrin was also observed not to hinder the conversion of linoleic acid to arachidonic acid and was observed to promote growth in rats when fed with minimal levels of linoleic acid (Ref. 5). In one study with premature infants (Ref. 6), tributyrin was readily absorbed and caused no untoward effects. Total United States poundage of tributyrin used by the food industry in 1970 was 1,000 pounds. Given this small exposure, and the toxicology data in the literature, the agency has tentatively concluded that there is little human risk associated with the use of this ingredient as a synthetic flavoring substance and adjuvant in food at levels that are now current or that might reasonably be expected in the future. Therefore, the agency is proposing to affirm as GRAS the use of tributyrin as a flavoring agent in food under conditions of current good manufacturing practice.

Because no food-grade specifications exist for glyceryl monostearate, glyceryl monooleate, and monosodium phosphate derivatives of mono- and diglycerides at the present time, the agency will work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specifications for these ingredients. If acceptable specifications are developed, the agency will incorporate them into the regulations at a later date. Until specifications are developed, FDA has determined that the public health will be adequately protected if glyceryl monostearate, glyceryl monooleate, and monosodium phosphate derivatives of mono- and diglycerides comply with the description in the proposed regulations and are of food-grade purity (21 CFR 170.30(h)(1) and 182.1(b)(3)).

Additionally, FDA is not including in the proposed GRAS affirmation regulations for mono- and diglycerides, diacetyl tartaric acid esters of mono- and diglycerides, monosodium phosphate derivatives of mono- and diglycerides, glyceryl monstearate, glyceryl monooleate, triacetin, and tributyrin the levels of use reported in the 1971 NSA/NRC food survey for these ingredients. Except for tributyrin, both FASEB and the agency have concluded that a large margin of safety exists for the use of these substances, and that a reasonable foreseeable increase in the level of use of these substances will not adversely affect human health. FDA reached the same conclusions for tributyrin after its own evaluation of this substance.

The agency is also not including in the proposed GRAS affirmation regulatons for mono- and diglycerides and glyceryl monostearate the food categories of use reported for the ingredients in the 1971 NAS/NRC survey. The survey reported the use of these ingredients in a large number of food categories, including food categories containing high consumption food products. The agency has concluded that expansion of use of these ingredients into additional food categories would not result in a significant increase in total consumption of these ingredients, and that any such increase in consumption would be covered by available safety information.

Finally, the agency is not including in the proposed GRAS affirmation regulation for glyceryl monstearate the technical effects reported for the ingredient in the 1971 NAS/NRC survey. The ingredient is commonly used for a wide variety of technical effects in food, including such nonspecific technical effects as a processing aid and a stabilizer and a thickener. The agency concludes that an expansion in the use of glyceryl monostearate in food because of use for new technical effects is unlikely because the technical effects for which it is not currently used are highly specific, and, given glyceryl monostearate's physical and chemical properties, unsuitable for this ingredient. Furthermore, the current wide margin of safety for the use of glyceryl monostearate in food assures that any increase in consumption resulting from the use of this ingredient for additional technical effects in food would be safe.

Therefore, the agency is proposing to affirm the GRAS status of these ingredients when used under current good manufacturing practice conditions of use in accordance with § 184.1(b)(1) (21 CFR 184.1(b)(1)). To make clear, however, that affirmation of the GRAS status of these substances is based on the evaluation of currently known uses or limited uses, the proposed regulations set forth technical effects for mono- and diglycerides and technical effects and food categories for diacetyl tartaric acid esters of mono- and diglycerides, monosodium phosphate derivatives of mono- and diglycerides, glyceryl monooleate, triacetin, and tributyrin that FDA evaluated.

In the **Federal Register** of September 7, 1982 (47 FR 39199), FDA proposed to adopt a general policy restricting the circumstances in which it will specifically describe conditions of use in regulations affirming substances as GRAS under 21 CFR 184.1(b)(1) or 186.1(b)(1). The agency proposed to amend tis regulations to indicate clearly that it will specify one or more of the current good manufacturing practice conditions of use in regulations for substances affirmed as GRAS with no limitations other than current good manufacturing practice only when the agency determines that it is appropriate to do so.

In the past, when a substance has been listed in Part 182 (21 CFR Part 182) as GRAS for both direct and indirect uses, FDA has proposed separate GRAS affirmation regulations in Parts 184 and 186 (21 CFR Parts 184 and 186) to govern its direct and indirect GRAS uses, respectively. Under § 184.1(a) (21 CFR 184.1(a)), however, ingredients affirmed as GRAS for direct food uses in Part 184 are considered to be GRAS for indirect uses without a separate listing in Part 186. Based on § 184.1(a), FDA has reconsidered its traditional practice and has concluded that the duplicative listing in Part 186 is unnecessary, as a general rule, and may cause confusion. Thus, unless safety considerations make it necessary to impose specific purity specifications or other restrictions on

the indirect use of a GRAS substance, FDA will no longer list in Part 186 substances that are affirmed as GRAS for direct use in Part 184. In keeping with this change in policy, FDA is not proposing a separate listing in Part 186 for the indirect uses of mono- and diglycerides. The indirect uses of mono- and diglycerides would be authorized under §§ 184.1(a) and 184.1505.

In the case of mono- and diglycerides, FDA believes that the general requirements that indirect GRAS ingredients be of a purity suitable for their intended use in accordance with § 170.30(h)(1) (21 CFR 170.30(h)(1)) and used in accordance with current good manufacturing practice are sufficient to ensure the safe use of these ingredients. Therefore, the agency has not proposed any specific purity specifications for their indirect use.

Although the policies discussed in the two preceding paragraphs are not inconsistent with FDA's current regulations, FDA published a proposal in the **Federal Register** of June 25, 1982 (47 FR 27817) to amend its procedural regulations in Parts 184 and 186 to reflect clearly these policies.

Copies of the scientific literature review and the reports of the Select Committee on glycerin and glycerides and the mutagenic evaluations of monosodium phosphate derivatives of mono- and diglycerides, glyceryl monostearate, and triacetin are available for review at the Dockets Management Branch (address above), and may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161, as follows:

Title	Order No.	Price code	Price [1]
Glycerin and glycerides (scientific literature review)	PB-221-227	A10	$17.00
Glycerin and glycerides (Select Committee report)	PB-254-536/AS	A03	6.50
Monosodium phosphate derivatives of mono- and diglycerides (mutagenic evaluation)	PB-245-505/AS	A03	6.50
Glyceryl monostearate (mutagenic evaluation)	PB-257-869/AS	A03	6.50
Triacetin (mutagenic evaluation)	PB-257-871/AS	A03	6.50

[1] Price subject to change.

These proposed actions do not affect the current use of these glycerides in pet food or animal feed.

The format of these proposed regulations is different from that in previous GRAS affirmation regulations. FDA has modified paragraph (c) of §§ 184.1101, 184.1323, 184.1505, 184.1521, 184.1901, and 184.1903 to make clear the agency's determination that GRAS affirmation is based upon current good manufacturing practice conditions of use, including both technical effects and food categories listed. This change has no substantive effect but is made merely for clarity.

The agency has determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal would have on small entities including small businesses and has determined that the effect of this proposal is to maintain current known uses of the substances covered by this proposal by both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal, and the agency has determined that the final rule, if promulgated, will not be a major rule as defined by the Order.

References

The following information has been placed on display in the Dockets Management Branch (address above) and may be reviewed by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Stoner, G. D., M. B. Shimkin, A. J. Kniazeff, J. G. Weisburger, E. K. Weisburger, and B. G. Gori, "Test for Carcinogenicity of Food Additives and Chemotherapeutic Agents by the Pulmonary Tumor Response in Strain A Mice," *Cancer Research*, 33:3069–3085, 1973.

2. Salmon, W. D. and D. H. Copeland, "The Occurrence of Gastric Lesions in the Rat as a Result of Feeding Tributyrin," *Journal of the National Cancer Institute*, 10:361–373, 1949–1959.

3. Wretland, A., "The Toxicity of Low-molecular Triglycerides," *Acta Physiologica Scandinavica*, 40:338–343, 1957.

4. Sylven, C. and B. Borgstrom, "Intestinal Absorption and Lymphatic Transport of Cholesterol in the Rat: Influence of the Fatty Acid Chain Length of the Carrier Triglyceride," *Journal of Lipid Research*, 10:351–355, 1969.

5. Mohrhauer, H. and R. F. Holman, "Metabolism of Linoleic Acid in Relation to Dietary Saturated Fatty Acids in the Rat," *Journal of Nutrition*, 91:528–534, 1967.

6. Snyderman, S. E., S. Morales, and L. E. Holt, Jr., "Fat Absorption in Premature Infants," *Archives of Disease in Childhood*, 30:83–84, 1955.

List of Subjects

21 CFR Part 172

Food additives, Food preservatives, Spices and flavorings.

21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), it is proposed that Parts 172, 182, and 184 be amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

§ 172.515 [Amended]

1. Part 172 is amended in § 172.515 *Synthetic flavoring substances and adjuvants* in paragraph (b) by removing "glyceryl monooleate" from the list of substances.

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

2. Part 182 is amended:

§ 182.60 [Amended]

a. In § 182.60 *Synthetic flavoring substances and adjuvants* by removing the entry for "Glycerol (glyceryl) tributyrate (tributyrin, butyrin)."

§ 182.90 [Amended]

b. In § 182.90 *Substances migrating to food from paper and paperboard products* by removing the entry for "Mono- and diglycerides from glycerolysis of edible fats and oils."

§§ 182.1324, 182.1901, 182.4101, 182.4505, 182.4521 [Removed]

c. By removing § 182.1324 *Glyceryl monostearate*, § 182.1901 *Triacetin*, § 182.4101 *Diacetyl tartaric acid esters of mono- and diglycerides of edible fats and oils, or edible fat-forming acids*, § 182.4505 *Mono- and diglycerides of*

edible fats or oils, or edible fat-forming acids, and § 182.4521 *Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.*

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. Part 184 is amended:

a. By adding new § 184.1101, to read as follows:

§ 184.1101 Diacetyl tartaric acid esters of mono- and diglycerides.

(a) Diacetyl tartaric acid esters of mono- and diglycerides are composed of mixed esters of glycerin in which one or more of the hydroxyl groups of glycerin have been esterified by diacetyl tartaric acid and by fatty acids. The ingredient is prepared by the reaction of diacetyl tartaric anhydride with mono- and diglycerides that are derived from edible sources.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 98, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as an emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter and a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; dairy product analogs as defined in § 170.3(n)(10) of this chapter; and fats and oils as defined in § 170.3(n)(12) of this chapter.

b. By adding new § 184.1323, to read as follows:

§ 184.1323 Glyceryl monooleate.

(a) Glyceryl monooleate is the monoester of glycerin and oleic acid. It is prepared by esterification of oleic acid that is derived either from edible sources or from tall oil fatty acids meeting the requirements of § 172.862 of this chapter.

(b) FDA is developing food-grade specifications for glyceryl monooleate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter and a solvent and vehicle as defined in § 170.3(o)(27) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages and beverage bases as defined in § 170.3(n)(3) of this chapter; and meat products as defined in § 170.3(n)(29) of this chapter.

c. By adding new § 184.1324, to read as follows:

§ 184.1324 Glyceryl monostearate.

(a) Glyceryl monostearate (CAS Reg. No. 31566–31–1), also known as monostearin, is the monoester of glycerin and stearic acid. The commercial product is a mixture of variable proportions of glyceryl monostearate and glyceryl monopalmitate. Glyceryl monostearate is prepared by glycerolysis of certain fats or oils that are derived from edible sources or by esterification, with glycerin, of stearic acid that is derived from edible sources.

(b) FDA is developing food-grade specifications for glyceryl monostearate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

d. By adding § 184.1505, to read as follows:

§ 184.1505 Mono- and diglycerides.

(a) Mono- and diglycerides consist of a mixture of glyceryl mono- and diesters, and minor amounts of triesters, that are prepared from fats or oils or fat-forming acids that are derived from edible sources. The most prevalent fatty acids include lauric, linoleic, myristic, oleic, palmitic, and stearic. Mono- and diglycerides are manufactured by the reaction of glycerin with fatty acids or the reaction of glycerin with triglycerides in the presence of an alkaline catalyst. The products are further purified to obtain a mixture of glycerides, free fatty acids, and free glycerin that contains at least 90-percent-by-weight glycerides.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 201, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a dough strengthener as defined in § 170.3(o)(6) of this chapter; an emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter; a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; a solvent and vehicle as defined in § 170.3(o)(27) of this chapter; a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; a surface-active agent as defined in § 170.3 (o)(29) of this chapter; a surface-finishing agent as defined in § 170.3(o)(30) of this chapter; and a texturizer as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

e. By adding new § 184.1521, to read as follows:

§ 184.1521 Monosodium phosphate derivatives of mono- and diglycerides.

(a) Monosodium phosphate derivatives of mono- and diglycerides are composed of glyceride derivatives formed by reacting mono- and diglycerides that are derived from edible sources with phosphorus pentoxide followed by neutralization with sodium carbonate.

(b) FDA is developing food-grade specifications for monosodium phosphate mono- and diglycerides in cooperation with the National Academy of Sciences. In the interim, this

ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as an emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter; a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; and as a surface-active agent as defined in § 170.3(o)(29) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: dairy product analogs as defined in § 170.3(n)(10) of this chapter and soft candy as defined in § 170.3(n)(38) of this chapter.

f. By adding new § 184.1901, to read as follows:

§ 184.1901 Triacetin.

(a) Triacetin ($C_9H_{14}O_6$, CAS Reg. No. 102-76-1), also known as 1,2,3,-propanetriol triacetate or glyceryl triacetate, is the triester of glycerin and acetic acid. Triacetin can be prepared by heating glycerin with acetic anhydride alone or in the presence of finely divided potassium hydrogen sulfate. It can also be prepared by the reaction of oxgen with a liquid-phase mixture of allyl acetate and acetic acid using a bromide as a catalyst.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 337, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; a humectant as defined in § 170.3(o)(16) of this chapter; and a solvent and vehicle as defined in § 170.3(o)(27) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; alcoholic beverages as defined in § 170.3(n)(2) of this chapter; nonalcoholic beverages and beverages bases as defined in § 170.3(n)(3) of this chapter; chewing gum as defined in § 170.3(n)(6) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter; hard candy as defined in § 170.3(n)(25) of this chapter; gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

g. By adding new § 184.1903, to read as follows:

§ 184.1903 Tributyrin.

(a) Tributyrin ($C_{15}H_{26}O_6$, CAS Reg. No. 60-01-5), also known as butyrin or glyceryl tributyrate, is the triester of glycerin and butyric acid. It is prepared by esterification of glycerin with excess butyric acid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 416, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St., NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a flavoring agent as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; alcoholic beverages as defined in § 170.3(n)(2) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; fats and oils as defined in § 170.3(n)(12) of this chapter; frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter; gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

The agency is unaware of any prior sanction for the use of these ingredients in foods under conditions different from those identified in this document or Part 181 (21 CFR Part 181). Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The action proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), and the failure of any person to come forward with proof of an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on it later. Should any person submit proof of the existence of a prior sanction, the agency hereby proposes to recognize such use by issuing an appropriate final rule under Part 181 or affirming it as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

Interested persons may, on or before April 11, 1983, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of all comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 18, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-3212 Filed 2-7-83; 8:45 am]

BILLING CODE 4160-01-M

---

21 CFR Parts 182 and 184

[Docket No. 78N-0348]

Glycerin; Affirmation of GRAS Status as a Direct Human Food Ingredient

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to affirm that glycerin is generally recognized as safe (GRAS) as a direct human food ingredient. The safety of this ingredient has been evaluated under a comprehensive safety review conducted by the agency. A proposal to affirm certain glycerides as GRAS appears elsewhere in this issue of the **Federal Register.**

DATE: Comments by April 11, 1983.

ADDRESS: Comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Susan Thompson, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive review of human food ingredients classified as GRAS or subject to a prior sanction. The agency has issued several notices and proposals (see the **Federal Register** of July 26, 1973 (38 FR 20040)) initiating this review, under which the safety of glycerin has been evaluated. In accordance with the provision of § 170.35 (21 CFR 170.35), the agency proposes to affirm the GRAS status of this ingredient.

Glycerin is the polyhydric alcohol 1,2,3-propanetriol, also know as glycerol, glycerine, glycyl alcohol, or 1,2,3-trihydroxypropane. It is a component of both animal and vegetable fats. In the animal, glycerin can be formed from ingested carbohydrate and from glycogen by glycolysis, and from fats and other lipids by hydrolysis. Glycerin may be prepared as a byproduct in the manufacture of soaps, fatty acids, and fatty alcohols from hydrolysis of fats and oils. It may also be produced by microbial fermentation of sugars. Synthetic glycerin is manufactured by chlorination or oxidation of propylene gas, through an allyl chloride, acrolein, or propylene oxide intermediate or, on a smaller scale, by hydrogenolysis of carbohydrates.

Glycerin was listed as GRAS as a miscellaneous substance in a regulation published in the **Federal Register** of November 20, 1959 (24 FR 9368). Subsequently, it was reclassified as a miscellaneous and general purpose food additive in a regulation published in the **Federal Register** of January 31, 1961 (26 FR 938), and reclassified and recodified as a multiple purpose GRAS food substance in a regulation published in the **Federal Register** of March 15, 1977 (42 FR 14640). Glycerin was also listed as GRAS as a substance migrating to food from paper and paperboard products used in food packaging in a regulation published in the **Federal Register** of June 17, 1961 (26 FR 5421). Glycerin is currently listed as GRAS in § 182.1320 (21 CFR 182.1320) as a multiple purpose GRAS food substance and in § 182.90 (21 CFR 182.90) as a substance migrating to food from paper and paperboard products. The Meat Inspection Division of the U.S. Department of Agriculture (USDA) permits the use of glycerin to inhibit drying for seasoning and curing mixes and to manufacture mono- and diglycerides in an amount sufficient for the purpose. The standard of identity for vanilla extract (21 CFR 169.175) lists glycerin as an optional ingredient.

Glycerol is listed in the following food additive regulations: In 21 CFR 175.300 (resinous and polymeric coatings) as a component in the preparation of rosin esters, as a polyhydric alcohol for forming polyester resins, and as a plasticizer; in 21 CFR 175.320 (resinous and polymeric coatings for polyolefin films) as a polyhydric alcohol for making polyester resins; in 21 CFR 176.210 (defoaming agents used in the manufacture of paper and paperboard) as a substance to react with fats, oils, and fatty acids to form mono- and diglycerides; in 21 CFR 177.2420 (polyester resins, cross-linked) as a polyol used in the formation of cross-linked polyester resins; and in 21 CFR 177.2800 (textiles and textile fibers) as a substance to react with fats, oils, and fatty acids in the preparation of textiles and textile fibers. Synthetic glycerin, produced by hydrogenolysis of carbohydrates, is listed in 21 CFR 172.866 as a direct food additive and in 21 CFR 178.3500 as a component of articles intended for use in packaging materials for food.

In 1971, the National Academy of Sciences/National Research Council (NAS/NRC) surveyed a representative cross-section of food manufactuers to determine the specific foods in which glycerin is used, the levels of usage, and the total poundage. The survey revealed that glycerin is used in half of the food categories listed in 21 CFR 170.3. NAS/NRC combined this manufacturing information with information on consumer consumption of foods to obtain an estimate of consumer exposure to this ingredient. FDA estimates from the NAS/NRC survey that the total amount of this ingredient used in food in 1970 was approximately 10.8 million pounds (4.9 million kilograms (kg)) or about 3 times that used in 1960.

Glycerin and glycerides have been the subject of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavioral effects, (12) detection, and (13) processing. A total of 1,817 abstracts on glycerin and glycerides was reviewed, and 103 particularly pertinent reports from the literature survey have been summarized in a scientific literature review.

Information from the scientific literature review and other sources has been summarized in a report to FDA by the Select Committee on GRAS Substances (the Select Committee), which is composed of qualified scientists chosen by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (FASEB). The members of the Select Committee have evaluated all the available safety information on glycerin.[1] In the Select Committee's opinion:

> Glycerin is a component of dietary fat. It has been subjected to extensive short- and long-term toxicological study. The available information on the acute and chronic effects of glycerin demonstrates that no pathological lesions or other adverse effects occur in experimental animals and man at oral levels of glycerin that are orders of magnitude greater than those now consumed. The available information indicates that the incidence of allergic or hypersensitivity reactions to glycerin is low.[2]

The Select Committee concludes that there is no evidence in the available information on glycerin that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used at levels that are now current or that might reasonably be expected in the future.[3]

FDA has undertaken its own evaluation of all available information on glycerin (including a mutagenic evaluation that was not available when the Select Committee formed its conclusion) and concurs with the conclusion of the Select Committee. The agency concludes that no change in the current GRAS status of this ingredient is justified. Therefore, the agency proposes to affirm the GRAS status of glycerin.

Additionally, FDA is proposing not to include in this GRAS affirmation regulation for glycerin the food categories, technical effects, and levels of use reported in the NAS/NRC 1971 survey for this ingredient. Both FASEB and the agency have concluded that a

[1] "Evaluation of the Health Aspects of Glycerin and Glycerides as Food Ingredients," Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1975, pp. 5-11. In the past, the agency presented verbatim the Select Committee's discussion of the biological data it reviewed. However, because the Select Committee's report is available at the Dockets Management Branch and from the National Technical Information Service, and because it represents a significant savings to the agency in publication costs, FDA has decided to discontinue presenting that discussion in the preamble to proposals that affirm GRAS status in accordance with current good manufacturing practice.

[2] *Ibid.*, p. 11.

[3] *Ibid.*

large margin of safety exists for the use of this substance, and that a reasonably foreseeable increase in the level of consumption of glycerin will not adversely affect human health. This conclusion is based on the fact that glycerin is currently widely used in food and is also a component of dietary fat, and that the Select Committee found that glycerin has a low order of toxicity in experimental animals and man. Therefore, the agency is proposing to affirm the GRAS status of glycerin when it is used under current good manufacturing practice conditions of use in accordance with §184.1(b)(1) (21 CFR 184.1(B)(1)).

In the **Federal Register** of September 7, 1982 (47 FR 39199), FDA proposed to adopt a general policy restricting the circumstances in which it will specifically describe conditions of use in regulations affirming substances as GRAS under 21 CFR 184.1(b)(1) or 186.1(b)(1). The agency proposed to amend its regulations to indicate clearly that it will specify one or more of the current good manufacturing practice conditions of use in regulations for substances affirmed as GRAS with no limitations other than current good manufacturing practice only when the agency determines that it is appropriate to do so.

In the past, when a substance has been listed in Part 182 (21 CFR Part 182) as GRAS for both direct and indirect uses, FDA has proposed separate GRAS affirmation regulations in Parts 184 and 186 (21 CFR Parts 184 and 186) to govern its direct and indirect GRAS uses, respectively. Under §184.1(a) (21 CFR 184.1(a)), however, ingredients affirmed as GRAS for direct food use in Part 184 are considered to be GRAS for indirect uses without a separate listing in Part 186. Based on § 184.1(a), FDA has reconsidered its traditional practice and has concluded that the duplicative listing in Part 186 is unnecessary, as a general rule, and may cause confusion. Thus, unless safety considerations make it necessary to impose specific purity specifications or other restrictions on the indirect use of a GRAS substance, FDA will no longer list in Part 186 substances that are affirmed as GRAS for direct use in Part 184. In keeping with this change in policy, FDA is not proposing a separate listing in Part 186 for the indirect uses of glycerin. The indirect uses of glycerin would be authorized under §§ 184.1(a) and 184.1320.

In the case of glycerin, FDA believes that the general requirements that indirect GRAS ingredients be of a purity suitable for their intended use in accordance with § 170.30(h)(1) (21 CFR 170.30(h)(1)) and used in accordance with current good manufacturing practice are sufficient to ensure the safe use of this ingredient. Therefore, the agency has not proposed any specific purity specifications for its indirect use.

Although the policies discussed in the two preceding paragraphs are not inconsistent with FDA's current regulations, FDA published a proposal in the **Federal Register** of June 25, 1982 (47 FR 27817) to amend its procedural regulations in Parts 184 and 186 to reflect clearly these policies.

Copies of the scientific literature review, reports of mutagenic and teratogenic tests, and the report of the Select Committee on glycerin are available for review at the Dockets Management Branch (address above), and may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161, as follows:

Title	Order No.	Price code	Price[1]
Glycerin and glycerides (scientific literature review).	PB-221-227	A10	$18.00
Glycerin and glycerides (Select Committee report).	PB-254-536/AS	A03	7.50
Glycerin (mutagenic evaluation).	PB-245-479/AS	A03	7.50
Glycerin (teratogenic evaluation).	PB-234-876/AS	A03	6.50

[1] Price subject to change.

This proposed action does not affect the current use of glycerin in pet food or animal feed.

The format of this proposed regulation is different from that in previous GRAS affirmation regulations. FDA has modified paragraph (c) of § 184.1320 to make clear the agency's determination that GRAS affirmation is based upon current good manufacturing practice conditions of use. This change has no substantive effect but is made merely for clarity.

The agency has determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal would have on small entities including small businesses and has determined that the effect of this proposal is to maintain current known uses of the substance covered by this proposal by both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal, and the agency has determined that the final rule, if promulgated, will not be a major rule as defined by that Order.

List of Subjects

21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), it is proposed that Parts 182 and 184 be amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. Part 182 is amended:

§ 182.90 [Amended]

a. In § 182.90 *Substances migrating to food from paper and paperboard products* by removing the entry for "Glycerin."

§ 182.1320 [Removed]

b. By removing § 182.1320 *Glycerin.*

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

2. Part 184 is amended by adding new § 184.1320, to read as follows:

§ 184.1320 Glycerin.

(a) Glycerin ($C_3H_8O_3$, CAS Reg. No. 56–81–5) is the polyhydric alcohol 1,2,3-propanetriol, also known as glycerol, glycerine, glycyl alcohol, 1,2,3-propanetriol, and 1,2,3-trihydroxypropane. Glycerin is prepared by microbial fermentation of sugars; or is prepared by hydrolysis of oils and

fats that are derived from edible sources during the production of soaps, fatty acids, and fatty alcohols; or is synthesized from propylene through one of three intermediates: allyl chloride, acrolein, and propylene oxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 136, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

The agency is unaware of any prior sanction for the use of this ingredient in foods under conditions different from those identified in this document. Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The action proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), and the failure of any person to come forward with proof of an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on it later. Should any person submit proof of the existence of a prior sanction, the agency hereby proposes to recognize such use by issuing an appropriate final rule under Part 181 (21 CFR Part 181) or affirming it as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

Interested persons may, on or before April 11, 1983 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of all comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 18, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-3213 Filed 2-7-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 184

[Docket No. 79N-0140]

GRAS Status of Rennet; Tentative Final Rule

Correction

In FR Doc. 82-32727 beginning on page 54454 in the issue of Friday, December 3, 1982, make the following correction:

On page 54456, in § 184.1685(c)(2), the 19th and 20th lines from the top of the third column, now reading "as defined in § 170.3(n)(31) of this chapter." should have read "as defined in § 170.3(n)(22) of this chapter; and milk products as defined in § 170.3(n)(31) of this chapter.".

BILLING CODE 1505-01-M

21 CFR Part 358

[Docket No. 82N-0214]

OTC Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis; Establishment of a Monograph

Correction

In FR Doc. 82-32846 beginning on page 54646 in the issue of Friday, December 3, 1982, make the following corrections:

1. On page 54659, third column, in the third and fourth lines from the top of the page, "20 percent coal tar zinc oxide paste" should have read "20 percent coal tar in zinc oxide paste".

2. On page 54660, the fourth line from the top of the third column now reading "(39) OTC Volume 160314" should have read "(39) OTC Volume 160134".

3. On page 54662, middle column, in the 15th line from the top of the page, "selenium suspension" should have read "selenium sulfide suspension".

4. On page 54669, third column, in the 11th line, "irritation of" should have read "irritation or".

5. On page 54670, third column, in the 26th line from the top of the page, "(Ref. 1)" should have read "(Ref. 2)".

6. On page 54675, first column, under **References**, item (5), the title of the article cited should have read "Comparative Effects of Hydrocortisone and Hydrocortisone-Coal Tar Extract Creams in Cases of Atopic Dermatitis".

BILLING CODE 1505-01-M

21 CFR Part 358

[Docket No. 82N-0214]

Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis for Over-the-Counter Human Use; Advance Notice of Proposed Rulemaking; Extension of Time for Comments and Reply Comments

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking; extension of comment periods.

SUMMARY: The Food and Drug Administration (FDA) is extending to April 4, 1983, the comment period and to May 4, 1983, the reply comment period for the advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) drug products for the control of dandruff, seborrheic dermatitis, and psoriasis. This action is being taken in response to a request to allow more time for interested persons to address adequately several important issues raised by the Panel and to consult experts so that more informed comments may be submitted to FDA.

DATES: Written comments by April 4, 1983, and reply comments by May 4, 1983.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFN-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 3, 1982 (47 FR 54646), FDA issued an advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis. This advance notice of proposed rulemaking, which was based on the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products, is part of the ongoing review of OTC drug products conducted by the agency. Interested persons were given until March 3, 1983, to comment on the advance notice of proposed rulemaking and until April 4, 1983, for reply comments.

In response to the proposal, The Proprietary Association requested a 30-day extension of the comment period to