FERC ¶ 61,140 (1988); *Natural Gas Pipeline Co. of America*, 45 FERC ¶ 61,148 (1988); *Trunkline Gas Co.*, 44 FERC ¶ 61,407 (1988); *El Paso Natural Gas Co.*, 43 FERC ¶ 61,576 (1988). This litigation exception was merely enunciated again in Order No. 500–F. The revised tariff language providing for the litigation exception which a pipeline must file does not, as Michigan asserts, require its customers to pay costs which are unknown and unmeasurable. The revised tariff language will not itself require the customers to pay any costs. It simply provides the customers notice that for contracts which are in litigation on March 31, 1989, the pipeline may pursue the litigation to its natural end and then file to recover eligible costs. When the subsequent filing is made, the costs will be known and measurable. The Commission believes the litigation exception will decrease the likelihood of hasty and expensive settlements at the expense of the parties' foregoing whatever avenues of legal redress are available.

Michigan's other arguments relating to retroactive ratemaking and the status of interruptible customers have been raised previously in the Order No. 500 proceedings and need not be discussed again here. Regulation of Natural Gas Pipelines After Partial Wellhead Decontrol, Order No. 500, 52 FR 30334 and 52 FR 35,539, FERC Stats. & Regs. ¶ 30,761 (1987); *United Gas Pipe Line Co.* 41 FERC ¶ 61,381 (1987), *reh denied*, 42 FERC ¶ 61,197 (1988).

For the reasons discussed above, the Commission denies the requests for rehearing filed on January 9, 1989, by CNG Transmission Corporation, Rochester Gas and Electric Corporation and Connecticut Natural Gas Corporation, United Distribution Companies, and the State of Michigan and the Michigan Public Service.

By the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 89–3947 Filed 2–17–89; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172, 182, and 184

[Docket No. 78N–0349]

Certain Glycerides; Affirmation of Gras Status

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that the use of mono- and diglycerides, diacetyl tartaric acid esters of mono- and diglycerides, monosodium phosphate derivatives of mono- and diglycerides, glyceryl monostearate, glyceryl monooleate, triacetin (glyceryl triacetate), and tributyrin (glyceryl tributyrate) as direct human food ingredients is generally recognized as safe (GRAS). The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective March 23, 1989. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1101(b), 184.1505(b), 184.1901(b), and 184.1903(b); effective March 23, 1989.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 8, 1983 (48 FR 5751), FDA published a proposal to affirm that mono- and diglycerides, diacetyl tartaric acid esters of mono- and diglycerides, monosodium phosphate derivatives of mono- and diglycerides, glyceryl monostearate, glyceryl monooleate, triacetin (glyceryl triacetate), and tributyrin (glyceryl tributyrate) and GRAS for use as direct human food ingredients. FDA published this proposal in accordance with its announced review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the report of the Select Committee on GRAS Substances (the Select Committee) on glycerin and glycerides have been made available for public review in the Dockets Management Branch (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday. Copies of these documents are also available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status 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, FDA gave public notice that it was unaware of any prior-sanctioned food uses for these ingredients other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of these ingredients recognized by the issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181), or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate. FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for mono- and diglycerides, diacetyl tartaric acid esters of mono- and diglycerides, monosodium phosphate derivatives of mono- and diglycerides, glyceryl monosterate, glyceryl monooleate, triacetin, and tributyrin were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for the use of these ingredients under conditions different from those set forth in this final rule has been waived.

FDA received three comments in response to the proposed rule. A summary of these comments and the agency's responses follow:

1. One comment requested that proposed § 184.1101 *Diacetyl tartaric acid esters of mono- and diglycerides* be amended by inserting, in parenthesis, the acronym "DATEM" immediately following the title and after the name of the ingredient where it appears in the first section of paragraph (a) of the regulation. The comment stated that the long chemical name by which the ingredient is described in the regulation places a burden on food manufacturers who must label their products with this name. The comment requested that the acronym "DATEM" be incorporated in the final rule to permit public exposure over a period of time and to eventually lead to acceptance of the acronym as the common or usual name for this ingredient.

The agency agrees that an acronym could be used in combination with the name of the ingredient, and that the acronym could become the common or usual name of that ingredient. The agency initially believed that the proposed introduction of the acronym "DATEM" as a synonym for diacetyl tartaric acid esters of mono- and

diglycerides would be appropriate. The agency finds, however, that this use of the acronym "DATEM" could cause confusion with the use of this term in Europe, where it stands for a wide variety of mixed esters (mono- and diglycerides of acetic acid and tartaric acid). This, the agency is rejecting this request. FDA believes that an alternative acronym may be appropriate. Any interested person may petition FDA to adopt an alternative acronym.

2. The second comment stated that diacetyl tartaric acid esters of mono- and diglycerides are used as emulsifiers in nonalcoholic beverages, as defined in § 170.3(n)(3), at levels up to 200 parts per million. The comment requested that the proposed GRAS affirmation regulation for this ingedient be amended to explicitly authorize this use.

FDA has considered the likely increase in exposure to diacetyl tartaric acid esters of mono- and diglycerides resulting from its use as anemulsifier in nonalcoholic beverages. The agency concludes that this additional use of diacetyl tartaric acid esters of mono- and diglycerides is supported by data from the review and is safe. Therefore, FDA is affirming this use as GRAS.

3. The third comment, from a trade association, stated that it had submitted information to the National Academy of Sciences/National Research Council (NAS/NRC) on the use of mono- and diglycerides and triacetin as formulation aids, and on the use of glyceryl monooleate as a flavoring agent, in chewing gum products. The association requested that the proposed regulations for these ingredients be amended in the final rule to authorize these uses in chewing gum products.

FDA has carefully considered this comment in the light of the safety data that have been accumulated for the GRAS review of these substances. The agency concludes that adequate safety data exist to assure that these ingredients may be safely used in chewing gum products as requested by the comment. Therefore, the agency has amended the final rule to include the requested uses to glyceryl monooleate, mono- and diglycerides, and triacetin in chewing gum products.

FDA is also modifying the proposed descriptions for glyceryl monooleate (§ 184.1323) and glyceryl monostearate (§ 184.1324) to make clear that these ingredients are mixture with other glyceryl esters of fatty acids that are present in commercial oleic acid and stearic acid, respectively.

In the proposal, FDA stated that it would work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specifications for glyceryl monooleate, glyceryl monostearate, and monosodium phosphate derivatives of mono- and diglycerides and would incorporate those specifications into the regulations when they were developed. To date, however, work on the specifications is still incomplete. Until the specifications are developed, these ingredients for direct food uses must comply with the descriptions in their respective regulations and be of food-grade purity (21 CFR 170.30(h)(1) and 182.1(b)(3)).

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (February 8, 1983; 48 FR 5751). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not recieved any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as defined by the Order. The agency has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

21 CFR Part 182

Food ingredients, Food packaging, Spices and flavorings.

21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, Parts 172, 182, and 184 are amended as follows:

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

1. The authority citation for 21 CFR Part 172 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

§ 172.515 [Amended]

2. Section 172.515 *Synthetic flavoring substances and adjuvants* is amended in paragraph (b) by removing the entry for "Glyceryl monooleate" from the list of substances.

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR Part 182 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

§ 182.60 [Amended]

4. Section 182.60 *Synthetic flavoring substances and adjuvants* is amended by removing the entry for "Glycerol (glyceryl) tributyrate (tributyrin, butyrin)."

§ 182.90 [Amended]

5. Section 182.90 *Substances migrating to food from paper and paperboard products* is amended by removing the entry for "Mono- and diglycerides from glycerolysis of edible fats and oils."

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

6. Section 182.1324 *Glyceryl monostearate,* § 182.1901 *Triacetin,* § 182.4101 *Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or 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* are removed.

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

7. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

8. New § 184.1101 is added to Subpart B 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 has 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), pp. 98–99, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Avenue NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L Street NW., Washington, DC 20005.

(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 and baking mixes as defined in § 170.3(n)(l) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) 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.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

9. New § 184.1323 is added to Subpart B to read as follows:

§ 184.1323 Glyceryl monooleate.

(a) Glyceryl monooleate is prepared by esterification of commerical oleic acid that is derived either from edible sources or from tall oil fatty acids meeting the requirements of § 172.862 of this chapter. It contains glyceryl monooleate ($C_{21}H_{40}O_4$, CAS Reg. No. 25496–72–4) and glyceryl esters of fatty acids present in commercial oleic acid.

(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 as 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; chewing gum as defined in § 170.3(n)(6) of this chapter; and meat products as defined in § 170.3(n)(29) of this chapter.

(d) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

10. New § 184.1324 is added to Subpart B to read as follows:

§ 184.1324 Glyceryl monostearate.

(a) Glyceryl monostearate, also known as monostearin, is a mixture of variable proportions of glyceryl monostearate ($C_{21}H_{42}O_4$, CAS Reg. No. 31566–31–1), glyceryl monopalmitate ($C_{19}H_{38}O_4$, CAS Reg. No. 26657–96–5) and glyceryl esters of fatty acids present in commercial stearic acid. 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) Prior sanctions for this ingredient different from the uses established in this section do not not exist or have been waived.

11. New § 184.1505 is added to Subpart B 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 in accordance with 5 U.S.C. 552(a). 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 20005.

(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 (GARS) 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 formulation aid as defined in § 170.3(o)(14) 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 stabilzer 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.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

12. New § 184.1521 is added to Subpart B to read as follows:

§ 184.1521 Monosodium phosphate derivatives of mono- and diglycerides.

(a) Monosodium phophate 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 (tetraphosphorus decoxide) 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.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

13. New § 184.1901 is added to Subpart B 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 oxygen with a liquid-phase mixture of allyl acetate and acetic acid using a bromide salt as a catalyst.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 337-338, as revised by the First Supplement to the 3d Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2102 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St., NW., Washington, DC 20005.

(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 formulation aid as defined in § 170.3(o)(14) of this chapter; and 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 and baking mixes 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 beverage 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 dessert and mixes as defined in § 170.3(n)(20) of this chapter; gelatins, puddings, and fillngs as defined in § 170.3(n)(22) of this chapter; hard candy as defined in § 170.3(n)(25) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

14. New § 184.1903 is added to Subpart B 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 specification of the Food Chemicals Codex, 3d Ed. (1981), p. 416, which is incorporated by reference in accordance with 5 U.S.C. 552(a). 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 20005.

(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 generaly 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.

(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 fillngs as defined in § 170.3(n)(22) of this chapter; and soft candy as defined in § 170.3(n)(39) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: February 13, 1989.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-3935 Filed 2-17-89; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 179

[Docket No. 86F-0418]

Irradiation in the Production, Processing, and Handling of Foods

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ethylene-vinyl acetate copolymers as a packaging material intended to contact food during irradiation. This action is in response to a petition filed by the Cryovac Division, W.R. Grace & Co.

DATES: Effective February 21, 1989; written objections and requests for a hearing by March 23, 1989.

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

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 21, 1986 (51 FR 42139), FDA announced that a food additive petition (FAP 7B3968) had been filed by the Cryovac Division, W.R. Grace & Co., P.O. Box 464, Duncan, SC 29334–0464, proposing that § 179.45 *Packaging materials for use during irradiation of prepackaged foods* (21 CFR 179.45) be amended to provide for the safe use of ethylene-vinyl acetate copolymers, complying with § 177.1350 *Ethylene-vinyl acetate copolymers* (21 CFR 177.1350), as a packaging material intended to contact food during irradiation.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that § 179.45 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before March 23, 1989 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Irradiation of foods, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Food Safety and Applied Nutrition, Part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR Part 179 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10; §§ 179.25 and 179.26 also are issued under secs. 402, 403, 703, 704, 52 Stat. 1046–1048 as amended, 1057, 67 Stat. 477 as amended (21 U.S.C. 342, 343, 373, 374); 21 CFR 5.10, 5.11.

2. Section 179.45 is amended by redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively, and by adding new paragraph (c) to read as follows:

§ 179.45 Packaging materials for use during the irradiation of prepackaged foods.

* * * * *

(c) Ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter. The ethylene-vinyl acetate packaging materials may be subjected to a dose of radiation, not to exceed 30 kilogray (3 megarads), incidental to the use of gamma, electron beam, or X-radiation in the radiation treatment of packaged foods.

* * * * *

Dated: February 13, 1989.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–3864 Filed 2–17–89; 8:45am]

BILLING CODE 4160–01–M

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21 CFR Part 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove Vet Labs Limited, Inc., from the list of sponsors of approved new animal drug applications (NADA's).

EFFECTIVE DATE: February 21, 1989.

FOR FURTHER INFORMATION CONTACT: John R. Markus, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3442.

SUPPLEMENTARY INFORMATION: Vet Labs Limited, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215, transferred several NADA's to Vet Labs, Inc. (53 FR 32610; August 26, 1988), and another NADA to Chemdex Inc. (53 FR 40728; October 18, 1988). As a result of these transfers, Vet Labs Limited, Inc., is no longer the sponsor of any approved NADA's.

The agency is amending 21 CFR 510.600(c) (1) and (2) to remove the sponsor listings for "Vet Labs Limited, Inc."

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR Part 510 continues to read as follows:

Authority: Secs. 512, 701(a) (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.