Excise Tax provision. This approach is too broad. The language and history of section 19(b) of the Act reflect an intent to limit an investment company's distributions of long-term capital gains to one with respect to each taxable year. While the Commission has broad exemptive rulemaking authority under the Act, it may not use that authority to override concerns specifically addressed by Congress. However, sections 6(c) and 19(b) do provide flexibility for the Commission to use its authority in unique circumstances not contemplated by Congress during passage of the Act.[16] In this instance, it was the enactment of the Excise Tax provision that gave to link the amendment to that legislation.

Conclusion

The purpose of the amendment is to aid RICs to avoid unnecessary taxation. The amendment allows RICs the flexibility to make decisions regarding certain tax consequences of distributing or not distributing long-term capital gains without the necessity of seeking exemptive relief from the Commission. Further, the Commission has modified the existing rule to clarify any ambiguity as to the timing or amount of distributions and the calculation of the maximum amount of a Spillover Distribution, and has adopted the technical corrections to the existing rule that were set forth in the Proposing Release.

Regulatory Flexibility Act Analysis

A summary of the Initial Regulatory Flexibility Analysis, prepared in accordance with 5 U.S.C. 603, regarding the proposed amendment to rule 19b–1 was published in the Proposing Release. No comments were received on that analysis. The Commission has prepared a Final Regulatory Flexibility Act Analysis, prepared in accordance with 5 U.S.C. 604, a copy of which may be obtained by contacting Brian M. Kaplowitz, Esq., Mail Stop 5–2, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549.

Paperwork Reduction Act

The Office of Management and Budget approved the amendment to rule 19b–1 on July 31, 1987.

[16] As is relevant here, section 6(c) of the Act provides that the Commission may grant an exemption from the provisions of the Act or any rule thereunder, "if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of this [Act]."

List of Subjects in 17 CFR Part 270

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Amendments to Rule

Part 270 of Chapter II of Title 17 of the Code of Federal Regulations is amended as shown.

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

1. The authority citation for Part 270 is amended by adding the following citation:

Authority: Secs. 38, 40, 54, Stat. 841, 842; 15 U.S.C. 80a–37, 80c–89; The Investment Company Act of 1940, as amended, 15 U.S.C. 80a–1 et seq.; unless otherwise noted.

* * * Section 270.19b–1 is also issued under secs. 6(c) (15 U.S.C. 80a–6(c)), 19 (a) and (b) (15 U.S.C 80a–19 (a) and (b)), and 38(a) (15 U.S.C. 80a–37(a)).

2. By amending § 270.19b–1 by revising paragraphs (a) and (c)(1)(iii), and adding a new paragraph (f) as follows:

§ 270.19b–1 Frequency of distribution of capital gains.

(a) No registered investment company which is a "regulated investment company" as defined in section 851 of the Internal Revenue Code of 1986 ("Code") shall distribute more than one capital gain dividend ("distribution"), as defined in section 852(b)(3)(C) of the Code, with respect to any one taxable year of the company, other than a distribution otherwise permitted by this rule or made pursuant to section 855 of the Code which is supplemental to the prior distribution with respect to the same taxable year of the company and which does not exceed 10% of the aggregate amount distributed for such taxable year.

* * * * *

(c) * * *

(1) * * *

(iii) The sale of an eligible trust security to maintain qualification of the Trust as a "regulated investment company" under section 851 of the Code,

* * * * *

(f) A registered investment company may make one additional distribution of long-term capital gains, as defined in the Code, with respect to any one taxable year of the company, which distribution is made, in whole or in part, for the purpose of not incurring any tax under section 4982 of the Code. Such additional distribution may be made prior or subsequent to any distribution otherwise permitted by paragraph (a) of this section.

By the Commission.

Jonathan G. Katz,

Secretary.

October 29, 1987.

[FR Doc. 87–25557 Filed 11–4–87; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 86C–0495]

MICA; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of September 11, 1987, for the final rule that amended the color additive regulations to provide for the safe use of mica in dentifrices that are drugs as well as cosmetics. FDA also changed the fineness specification for mica to permit a larger average particle size distribution.

EFFECTIVE DATE: September 11, 1987.

FOR FURTHER INFORMATION CONTACT: JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–9463.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 11, 1987 (52 FR 29664), FDA amended the color additive regulations to provide for the safe use of mica in dentifrices that are drugs as well as cosmetics and also changed the fineness specification for mica to permit a larger average particle size distribution.

FDA gave interested persons until September 10, 1987, to file objections or requests for a hearing on this final rule. The agency received no objections or requests for a hearing. Therefore, FDA concludes that the final rule published in the **Federal Register** of August 11, 1987, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376)) and under authority delegated to the Commissioner of Food and Drugs (21

CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the August 11, 1987, final rule. Accordingly, the amendments to § 73.1496 (a)(1), (b), and (c) became effective September 11, 1987.

Dated: October 30, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-25582 Filed 11-4-87; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 184

[Docket No. 86G-0086]

Substances Affirmed as Generally Recognized as Safe; Glyceryl Behenate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that glyceryl behenate is generally recognized as safe (GRAS) for use as a formulation aid in excipient mixtures used in food prepared as tablets.

EFFECTIVE DATE: November 5, 1987.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety and Applied Nutrition, (HFF-334), 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: In accordance with § 170.35 (21 CFR 170.35), Gattefosse Etablissements, 36 Chemin de Genas, Saint Priest, France, submitted a petition (GRASP 6G0308) requesting that glyceryl behenate be affirmed as GRAS for use as an excipient in food prepared as tablets.

FDA published a notice of filing of this petition in the **Federal Register** of June 4, 1986 (51 FR 20354), advising that any comments should be submitted to the Dockets Management Branch (HFC-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. No comments were received in response to this notice.

Glyceryl behenate has no history of food use prior to 1958.

Identity

Glyceryl behenate is a mixture of glyceryl esters (glycerides) of commercial behenic acid. It contains primarily diglycerides (47 to 59 percent) but also triglycerides (26 to 38 percent) and a smaller amount of monoglycerides (10 to 20 percent). Glyceryl behenate is similar in composition to the emulsifying agent mono- and diglycerides of edible fats and oils, or edible fat-forming acids (mono- and diglycerides), which is listed as GRAS in § 182.4505 (21 CFR 182.4505). However, glyceryl behenate contains a higher proportion of triglycerides than does mono- and diglycerides and also contains behenic acid as its primary fatty acid. Behenic acid is not commonly found in traditional edible fats and oils, although it is found in fully hydrogenated rapeseed oil, whose use is affirmed as GRAS in § 184.1555.

The notice of filing in this proceeding used the name "glyceryl behenate" to represent the material that is the subject of the petition. The agency has considered this name to be appropriate primarily for simplicity, although the material is actually not a single chemical substance.

Manufacturing Process

Glyceryl behenate is manufactured by heating a mixture of glycerin and behenic acid (a saturated C_{22} fatty acid). The reaction can proceed with or without the use of a solvent and catalysts. Nevertheless, solvents and catalysts, such as those currently used in the manufacture of fatty acid derivatives, may be used in the manufacture of this ingredient.

Commercial behenic acid, which is one of the raw materials for manufacture of glyceryl behenate, is produced from hydrogenated rapeseed oil and has the approximate composition of 88 percent behenic acid, 10 percent arachidic acid and oleic acid, and 2 percent fatty acids with a higher carbon number than C_{22} (such as lignoceric acid). It may also contain a trace amount of erucic acid but at a level of less than 1 percent.

Technical Effects and Use Levels

The proposed use of the substance is as a component of excipient mixtures used in foods prepared as tablets. The technical properties of the additive in excipient formulations are similar to those of other fatty acid glycerides. Fatty acid glycerides, in general, are excellent lubricants, have good binding effect, have good flowing potency, eliminate anv cleavage problem, and are totally inert toward active ingredients.

The petitioner stated that the normal use level of the substance will be 1 to 4 percent of total tablet weight, but that in some special cases, such as in sustained release formulations, the use level may be 10 to 20 percent. The petition contains no information that would clearly demonstrate the existence of a technological self-limiting use level.

Estimated Daily Intake

The petitioner stated that the typical dosage of vitamin pills is one or two tablets per day, but that individuals taking different vitamins in separate pills may take as many as six tablets per day.

FDA sponsored a telephone survey of vitamin/mineral supplement use in 1980 (Stewart et al., *Journal of the American Dietetic Association*, pp. 1585-1590, December 1985). This survey, although not a definitive survey of vitamin/mineral supplement use, provides the best data available for estimating potential consumption of glyceryl behenate. The survey estimated that 40 percent of U.S. consumers over 16 years of age ingest at least one supplement per day, and that the median intake of these users is one supplement per day. Using the middle value of the range of glyceryl behenate content for tablets, which is 10 percent, and using the median intake of one supplement having a typical table weight of 600 milligrams (mg) per day, the agency estimates that the likely chronic, daily intake for glyceryl behenate would be 60 mg per person per day.

In its safety review of glyceryl behenate, the agency's major concern was the potential increase in consumption of behenic acid that would result from the petitioned use of glyceryl behenate. Because 60 mg of glyceryl behenate contain about 46 mg of behenic acid, the estimated daily intake for behenic acid from this use would be 46 mg per person per day.

Safety Information

The petition cited the GRAS status of fully hydrogenated rapeseed oil (21 CFR 184.1555(a)) and superglycerinated fully hydrogenated rapeseed oil (21 CFR 184.1555(b)), and the data supporting the GRAS status of these ingredients (previously submitted in GRAS petition 4G0036), to support the safety and GRAS status of glyceryl behenate. Included in this data was a 90-day subchronic study in rats of fully hydrogenated rapeseed oil, which supported a daily intake of 189 mg of behenic acid per person after applying a 1,000-fold safety factor. This figure is significantly higher than the estimated daily intake for behenic acid (46 mg per person per day), as stated above, from the petitioned use of glyceryl behenate.

Fully hydrogenated rapeseed oil is a triglyceride, while superglycerinated fully hydrogenated rapeseed oil and glyceryl behenate are mixtures of mono-, di-, and triglycerides. Both fully hydrogenated rapeseed oil and superglycerinated fully hydrogenated rapeseed oil have the same fatty acid composition, which is a mixture of saturated fatty acids (from C_{18} to C_{24}),

with behenic acid accounting for about 42 percent.

Although the percentages of fatty acids in these two oils are different from that in glyceryl behenate, the types of fatty acids in the three oils are the same because they are all derived from fully hydrogenated rapeseed oil. The only difference among these oils is in the relative proportions of the fatty acids. Furthermore, because superglycerinated fully hydrogenated rapeseed oil and glyceryl behenate have similar percentage distributions of mono-, di-, and triglycerides, they have similar physical properties. Based on the similarity between glyceryl behenate and fully hydrogenated rapeseed oil and superglycerinated fully hydrogenated rapeseed oil and on its review of the information in GRAS petition 4G0036, FDA concludes that the information that supports the GRAS status of the use of the latter two substances can be relied upon in deciding whether the petitioned use of glyceryl behenate is GRAS.

Conclusions

The agency has evaluated all the information in the petition along with other available information that relates to the petitioned use of glyceryl behenate and has reached the following conclusions:

1. Glyceryl behenate is not GRAS based upon history of common use in food.

2. Glyceryl behenate is safe for use in tablets based on FDA's evaluation of information on the manufacturing process, the chemical composition, the estimated consumer exposure, and the toxicity of glyceryl behenate, fully hydrogenated rapeseed oil, and superglycerinated fully hydrogenated rapeseed oil.

3. Glyceryl behenate is GRAS based on scientific procedures. Glyceryl behenate is as safe as fully hydrogenated rapeseed oil and superglycerinated fully hydrogenated rapeseed oil. As noted above, glyceryl behenate has a similar percentage distribution of mono-, di-, and triglycerides as that in superglycerinated fully hydrogenated rapeseed oil and is composed of glycerides of the same fatty acids as those found in fully hydrogenated rapeseed oil and superglycerinated fully hydrogenated rapeseed oil. FDA affirmed that the use of the latter two oils is GRAS on the basis of scientific procedures (42 FR 48335 September 23, 1977). FDA is affirming that the use of glyceryl behenate as a formulation aid is GRAS on the basis of this material's similarity in composition to these oils.

4. Like other fatty acid glycerides, glyceryl behenate is effective for use in excipient formulations.

5. The material affirmed as GRAS is food-grade glyceryl behenate conforming to the identity and specifications set forth in the regulation below.

Therefore, the agency is affirming that when done in accordance with good manufacturing conditions, the use of glyceryl behenate as a formulation aid in excipient formulations for tablets is GRAS under § 184.1(b)(1). The agency is including the technical effect and food use in the regulation to make clear that the affirmation of the GRAS status of this material is based on the evaluation of limited uses.

Environmental Effects

The agency has carefully considered the potential environmental effects of this action and 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. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Economic Effects

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this rule would have on small entities including small businesses and has determined that the effect of this final rule is to provide a new use for glyceryl behenate. 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, the economic effects of this rule have been analyzed, and FDA has determined that the rule is not a major rule as defined by that order. A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch (address above).

List of Subjects in 21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 184 is amended as follows:

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

1. 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.

2. Part 184 is amended by adding new § 184.1328 to read as follows:

§ 184.1328 Glyceryl behenate.

(a) Glyceryl behenate is a mixture of glyceryl esters of behenic acid made from glycerin and behenic acid (a saturated C_{22} fatty acid). The mixture contains predominantly glyceryl dibehenate.

(b) The ingredient meets the following specifications:

(1) 10 to 20 percent monoglyceride, 47 to 59 percent diglyceride, 26 to 38 percent triglyceride, not more than 1 percent free glycerin, and not more than 2.5 percent free fatty acids.

(2) Behenic acid. Between 80 and 90 percent of the total fatty acid content.

(3) Acid value. Not more than 4.

(4) Saponification value. Between 145 and 165.

(5) Iodine number. Not more than 3.

(6) Heavy metals (as Pb). Not more than 10 parts per million.

(c) In accordance with § 184.1(b)(1) of this chapter, the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient is 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 formulation aid, as defined in § 170.3(o)(14) of this chapter.

(2) The ingredient is used in excipient formulations for use in tablets at levels not to exceed good manufacturing practice.

Dated: October 30, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–25583 Filed 11–4–87; 8:45 am]

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