21 CFR Part 184

[Docket No. 82G-0207]

Direct Food Substances Affirmed as Generally Recognized as Safe; Low Erucic Acid Rapeseed Oil

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that low erucic acid rapeseed oil (LEAR oil) (maximum 2 percent erucic acid) and partially hydrogenated LEAR oil are generally recognized as safe (GRAS) for use as fats and oils in food. This action responds to a petition filed by the Canadian Government and to comments filed in response to the notice of filing of the petition.

EFFECTIVE DATE: January 28, 1985.

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SUPPLEMENTARY INFORMATION:

I. Introduction

In accordance with the procedures described in § 170.35 (21 CFR 170.35),

The Canadian Government, through its Research Branch, Agriculture Canada, Rm. 761, Sir John Carling Bldg., Ottawa, Ontario, Canada, K1A OC5, submitted a petition (0G0266) requesting affirmation of the GRAS status of the use as edible fats and oils of rapeseed oil with an erucic acid content of 5 percent of the component fatty acids and of the partially hydrogenated form of this oil.

The petition contains data and information on food-grade specifications for this rapeseed oil; information on its present world-wide food use; and numerous published articles on the biochemistry, nutrition, and cardiac effects of rapeseed oils containing various amounts of erucic acid in animals such as the rat, mouse, chicken, dog, pig, and monkey. The animal studies included in the petition also compared the toxicity of these rapeseed oils with the toxicity of other vegetable oils. The petition also contains human clinical studies on the nutrition and metabolism of certain rapeseed oils.

FDA published a notice of filing of this petition in the Federal Register of August 13, 1982 (47 FR 35342). In that notice, FDA proposed to affirm as GRAS the use of rapeseed oil in which erucic acid makes up no more than 2 percent of the total fatty acid content. The agency has denominated this oil as low erucic acid rapeseed oil or LEAR oil. FDA gave interested persons an opportunity to review the petition and to submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

Seven comments were submitted in response to the notice of filing. The comments are discussed in section IV below.

II. Background

Edible oil was extracted from rapeseed in Asia before 2000 B.C. It was introduced into Europe as a cooking oil and as a food in the 17th century A.D. Rapeseed oil is currently used as an edible oil source in such European countries as the United Kingdom, Sweden, France, Germany, and Holland.

Canada began growing rapeseed during World War II to supply the edible oil market in Canada and abroad. Oil prepared from rapeseed grown before 1971 contained high levels of a fatty acid known as erucic acid. The amount of erucic acid in this rapeseed oil varied considerably but was generally in the range of 30 to 60 percent.

Nutritional studies in the 1950's indicated that high erucic acid rapeseed oil caused apparent nutritional deficiencies in rats in feeding experiments. The major concern raised by these studies was that the erucic acid component of rapeseed oil was associated with the predominant pathological effect found in these studies, cardiac lesions. As a result, high erucic acid rapeseed oil was never used as an edible oil in the United States. However, in 1977, FDA affirmed as GRAS the use of fully hydrogenated and superglycerinated fully hydrogenated rapeseed oils that contain levels of erucic acid of less than 0.1 percent (21 CFR 184.1555; 42 FR 48336; September 23, 1977).

Efforts were made in Canada during the 1960's to breed rapeseed plant varieties that had a low erucic acid content. By 1974, rapeseed oil varieties containing less than 5 percent erucic acid comprised nearly the entire Canadian rapeseed crop, and, according to the petition, by 1978, all Canadian rapeseed oil produced for food use contained less than 2 percent erucic acid. The rapeseed currently grown and used as an edible oil source in Europe contains less than 5 percent erucic acid.

The Joint Food and Agriculture Organization of the United Nations and World Health Organization's Codex Standard for edible erucic acid rapeseed oil (Ref. 43) includes rapeseed oils in which the erucic acid content is as high as 5 percent of the component fatty acids. Because of the erucic acid content of the rapeseed oils that are presently available, and because of its desire to ensure safety, however, FDA is restricting its GRAS affirmation to LEAR oil, which contains 2 percent or less erucic acid.

III. LEAR Oil

LEAR oil derives from rapeseed varieties that are strains of *Brassica napus* and *B. campestris*. LEAR oil, like other vegetable oils, consists primarily of triglycerides. The oil also contains small amounts of mono- and diglycerides and of free fatty acids. The fatty acid composition of LEAR oil is very similar to other vegetable oils such as olive oil, soybean oil, and sunflower seed oil, except for the presence of a small amount of erucic acid. Precise comparisons between LEAR oil and other vegetable oils cannot be made because vegetable oils vary in composition, depending upon the variety of the plant and its growing conditions. The principal fatty acids in LEAR oil are palmitic acid (2.5 to 6 percent), oleic acid (50 to 66 percent), linoleic acid (18 to 30 percent), and linolenic acid (6 to 14 percent).

LEAR oil can be used by itself as a salad or vegetable oil. However, LEAR oil is usually blended with other vegetable oils in the production of margarine, shortening, salad oil, and vegetable oil. Different blend formulations have physical properties that are suitable for different applications.

Although there is no current food consumption of LEAR oil in the United States, data in the petition indicate that in Canada in 1977, rapeseed oil constituted 33 percent of the fat used in margarine, 20 percent of the fat used in shortening, and 52 percent of the fat used in salad oil. At that time, rapeseed oil contained up to 5 percent, but mostly below 3 percent, erucic acid, and the estimated average daily per capita rapeseed oil intake by Canadians was 9.8 grams.

FDA has reviewed the information contained in the petition; the information it found in its own search of the scientific literature on the safety of LEAR oil and of rapeseed oils containing greater than 2 percent erucic acid; and the information submitted in the comments. This review has included over 200 published studies. FDA has found that LEAR oil does not produce the adverse effects produced by rapeseed oils containing higher levels of erucic acid, and that there are no significant differences in toxicity between LEAR oil and other vegetable oils.

FDA estimates that it is unlikely that a U.S. consumer would ingest more than 10 milligrams of erucic acid per kilogram body weight from LEAR oil. This estimate assumes that LEAR oil will compete favorably with other currently marketed vegetable oils in the U.S. marketplace and will represent as much as 50 percent of the consumer's total daily intake of vegetable oils. Thus, the consumer (a 60 kilogram adult) will ingest up to 30 grams of LEAR oil daily (Ref. 44). This estimate also assumes that all of the LEAR oil consumed will contain 2 percent erucic acid.

FDA is confident that this estimate does not understate potential exposure to erucic acid from the use of LEAR oil. For example, in comparison, FDA estimates that the average Canadian daily intake of erucic acid is only about one-fifth of this amount. Based upon 1977 consumption information, an average Canadian consumes about 10 grams per day of LEAR oil. Additionally, according to the petition, for 1982, the Canadian LEAR oil crop contained an average of 1.2 percent erucic acid. Thus, the estimated average level of consumption for Canadians is equivalent to a daily intake of 2 milligrams of erucic acid per kilogram body weight.

FDA finds that its estimated upper level of U.S. exposure to erucic acid, 10 milligrams of erucic acid per kilogram body weight, is safe for the following reasons:

(1) This level of exposure is much lower than the levels of daily intake of this substance at which, in the best available studies on LEAR oil, test animals do not show any adverse effects as compared to animals fed other vegetable oils. For example, Ref. 18 is a 2-year feeding study, with in utero exposure, in which rats were fed either LEAR or partially hydrogenated soybean oil. Rats were exposed to about 95 milligrams of erucic acid per kilogram body weight adverse effects as compared to those fed partially hydrogenated soybean oil. Likewise, pigs were exposed to about 30 milligrams of erucic acid per kilogram in Ref. 19. In this study, the pigs under test did not experience a significantly increased incidence of cardiac lipidosis or myopathy as compared to pigs fed a control diet containing no added oil. Additionally, monkeys were exposed to about 25 milligrams of erucic acid per kilogram in Ref. 20 and showed no myocardial lesions.

(2) The levels to which rats, pigs, and monkeys were exposed in the studies above do not necessarily represent the highest no-effect levels for these animals. The highest no-effect levels may actually be much higher than those reported above. However, because the studies did not feed higher levels of LEAR oils or LEAR oils containing higher levels of erucic acid to these animals, the actual no-effect levels cannot be determined.

For food additives, FDA normally employs a safety factor to arrive at a safe level below which the additive is considered to be appropriate for human consumption. However, large safety factors cannot be achieved for dietary macronutrients, such as vegetable oils, because exaggerated doses produce dietary imbalances in test animals. In addition, in this case, the agency believes that the direct comparison between the toxicity of LEAR oil to other vegetable oils provides a method for demonstrating the safety of LEAR oil. Therefore, FDA concludes that a safety factor is not needed in assessing the safety of LEAR oil.

Based on the considerations above, FDA concludes that there is a significant number of published studies on the safety of LEAR oil; that the data in these studies demonstrate that the use of this substance is safe; and that, therefore, the use of LEAR oil as a component of food can be affirmed as GRAS based upon scientific procedures (21 CFR 170.30).

IV. Summary of Comments on the Petition

FDA received a total of seven comments in response to the notice of filing on the petition. Five comments were from trade associations, one was from a food processor, and one was from a foreign embassy. Two of the comments expressed general agreement with the GRAS affirmation of LEAR oil, and one of these comments promised to submit data from scientific studies conducted in France that support that the use of rapeseed oil with up to 5 percent erucic acid is safe. (FDA has not received these studies and therefore finds no reason to consider the safety of any rapeseed oils other than LEAR oil.) Two comments strongly opposed the GRAS affirmation of LEAR oil. One of these comments cited numerous literature references in support of its opposition. Two additional comments expressed concerns about LEAR oil's safety and cited numerous literature references in support of their concerns. The final comment objected to some statements contained in the petition and submitted a report of a recently conducted 2-year chronic feeding study of fish oil, which included as one of its controls a group of rats fed LEAR oil (Ref. 18).

The petitioner submitted a rebuttal to those comments that opposed or raised concerns about the petition.

The results of the agency's review of the five comments that did not support GRAS affirmation are discussed below:

1. One of the comments stated that although the frequency of cardiac lesions associated with the consumption of LEAR oil was found to be insignificant in some rat feeding studies (Refs. 1, 2, and 3), other studies found the occurrence of such lesions to be dose dependent (Refs. 4, 5, and 6); dependent on the dosing period (Refs. 5 and 7 through 11); dependent on the type of LEAR oil used in the study (Refs. 4, 12, and 13); or related to the age (Ref. 4), sex (Ref. 12), and strain (no reference cited) of treated rats.

A. Dose Dependency

FDA has reviewed the references that the comment cites in support of its claim that a dose-dependent relationship exists for the occurrence of cardiac lesions in rats fed LEAR oil. Ref. 4 investigates whether such a relationship exists in rats fed rapeseed oils. Although this study did find a dose-dependent effect with a rapeseed oil (Span oil) which contains a higher percent of erucic acid than LEAR oil, the study did not show this relationship for the LEAR oil (Oro oil) used in the study.

Ref. 4 was conducted using male Sprague-Dawley rats. This strain and sex of rat is unusually susceptible to LEAR oil. The Sprague-Dawley strain requires a specific dietary fatty acid balance that is not fully satisfied by LEAR oil (Ref. 41). Thus, in a study the Sprague-Dawley rat developed heart lesions when fed LEAR oil, but the Chester Beatty rat did not (Ref. 41). Moreover, in a 2-year feeding study, Wistar rats did not develop any different heart pathology when fed LEAR oil than when fed partially hydrogenated soybean oil (Ref. 18).

Not only is the Sprague-Dawley strain more susceptible than other strains, but male Sprague-Dawley rats are more susceptible to cardiac lesions than female Sprague-Dawley rats when fed vegetable oils (Ref. 42). Therefore, the agency considers that these factors make Ref. 4 unreliable in determining whether there is a dose-dependent relationship between the occurrence of cardiac lesions in rats and the consumption of LEAR oil.

FDA has also reviewed Refs. 5 and 6 cited by the comment. These studies investigate the incidence of myocardial lesions in rats fed LEAR oil, high erucic acid rapeseed oil, and soybean oil (Ref. 5) or corn oil (Ref. 6). Both of these studies, however, included only one dose level for each oil and therefore did not investigate dose dependency for any of these oils. Thus, these references do not support the comment's claim that there is a dose-dependent occurrence of cardiac lesions associated with the consumption of LEAR oil.

B. Time Dependent

FDA has reviewed Refs. 5, 7, 8, 9, 10, and 11, which, according to the comment, demonstrate that the occurrence of heart lesions increases with time in rats fed LEAR oil. Ref. 5 compared the number of animals fed LEAR oil for 16 weeks that developed heart lesions to the number of rats fed LEAR oil for 28 weeks that developed these lesions. The myocardial lesions were found in 5 out of 10 animals after 16 weeks as compared to 6 out of 10 after 28 weeks. The difference in the number of animals with myocardial lesions for the two time periods is so small that the agency does not consider it to be significant. In Ref. 8, the authors concluded that the number of animals with lesions was greater after 1 year than after 6 months on either a 5 percent LEAR oil diet or a 5 percent peanut oil diet, but the number of rats with cardiac lesions was the same with both oils.

Ref. 10 concluded that after 12 months of feeding rats 5 percent peanut oil or 5 percent LEAR oil, myocardial changes in both groups of animals were comparable. Additionally, Refs. 7, 9, and 11 compared the time-related responses in rats fed LEAR oil with those in rats fed peanut oil and reported no differences between these two oils.

Thus, even though LEAR oil does cause a time-related increase in the incidence of heart lesions in rodents, in doing so it acts no differently than other food oils.

It is probable that the increase in the number of lesions seen over time is more the result of the aging process in rats than of any toxic properties of food oils. For example, Kaunitz and Johnson (Ref. 58) noted an increasing incidence of myocardial lesions with age in lifetime studies in rats fed several different animal and vegetable oils.

C. Dependency on Type of LEAR Oil

The agency has reviewed the references that the comment cited in support of its claim that heart lesions in rats are dependent on the type of LEAR oil ingested. The agency finds that Refs. 4, 12, and 13 compare the occurrence of cardiac lesions in rats fed LEAR oil with the occurrence of such lesions in rats fed rapeseed oils that contain more than 2 percent erucic acid. The latter oils are not LEAR oils and cannot be used to represent LEAR oil. Thus, these studies do not compare different types of LEAR oils and consequently provide no support for the claim that heart lesions in rats are dependent on the type of LEAR oil ingested.

D. Dependency on Age of Rats

The agency has reviewed Ref. 4 in conjunction with the comment's assertion that mature rats are more susceptible than young rats to heart lesions when fed LEAR oil. The agency finds that although the authors of this reference report the results of seven experiments, none of these experiments were on the susceptibility of young and mature rats to heart lesions from LEAR oil. Thus there are no data in this reference that support the assertion in the comment.

E. Sex and Strain Association

FDA has reviewed Ref. 12 and several additional published studies contained in the petition regarding the relationship between the sex (e.g., Ref. 42) and strain (e.g., Ref. 40) of rats fed LEAR and other vegetable oils and the incidence and severity of heart lesions. The agency agrees that male rats are generally more sensitive to heart lesions than female rats. In Ref. 12, for example, the male rats were more sensitive to heart lesions than female rats for all oils studied. However, in this study, there was no significant difference in the responses observed for LEAR oil as compared to soybean oil among animals of the same sex. FDA therefore disagrees with the comment that a greater sensitivity to heart lesions among male rats indicates that there is a health effect associated with the ingestion of LEAR oil.

Although the comment did not cite a reference in support of its claim that different rat strains show different degrees of susceptibility to LEAR oil, the agency has been aware that these differences exist (Refs. 40 and 41). As discussed above, some studies indicate that the male Sprague-Dawley rat is more susceptible to cardiac lesions when fed LEAR oil than when fed other vegetable oils (Refs. 29 and 32). On the other hand, a 2-year feeding study involving Wistar strain rats fed high levels of either LEAR oil of partially hydrogenated soybean oil did not reveal any differences in heart pathology caused by the two oils (Ref. 18).

The agency finds that the differences in susceptibility among rat strains do not indicate a potential hazard for humans from consumption of LEAR oil but instead are reflective of physiological and metabolic differences among those strains of rats (Refs. 40 and 41). Several factors support this finding. First, the fast growing Sprague-Dawley strain developed myocardial lesions when fed LEAR oil while the slower growing Chester Beatty strain did not. This differential sensitivity has been attributed to the Spargue-Dawley strain requiring a specific dietary fatty acid balance that is not fully satisfied by LEAR oil (Ref. 41). Furthermore, animal species other than the rat do not appear to be any more sensitive to LEAR oil than to other vegetable oils. For example, in a 24-week study with monkeys, no adverse cardiac effect from LEAR oil as compared to soybean oil was found (Refs. 20 and 34). Likewise, a 23-week study in pigs showed no adverse cardiac effect on animals fed LEAR oil as compared to those fed a control diet containing no added oil (Ref. 19). Thus, the agency concludes that the responses of various rat strains when fed LEAR oil are no different from the responses of various strains to other food oils and are not a basis for concern about the safety of LEAR oil for humans.

2. The same comment asserted that LEAR oil caused a marked change in the amounts of four cardiac lipids, diphosphatidylglycerol, sphinogomyelin, phosphatidylcholine, and phosphatidylethanolamine, in the hearts of the rats to which LEAR oil was fed and in the fatty acid composition of these cardiac lipids (Ref. 14).

The agency has evaluated Ref. 14 and notes that the study reports significant changes in the amounts of cardiac lipids (i.e., a decrease of phosphatidylcholine and phosphatidylethanolamine and an increase of diphosphatidylglycerol and sphinogomyelin) in the hearts of untrained (not-exercised) rats when fed 15 percent LEAR oil as compared to rats fed the same amount of sunflower seed oil. However, these effects on the cardiac phospholipid content were not observed in rats fed LEAR oil in the sme study when the rats were trained (exercised). Additionally, in two other studies of untrained rats (Refs. 15 and 16), there were no significant differences in the cardiac phospholipid content of rats fed 20 percent LEAR oil as compared to rats fed the same levels of corn oil, olive oil, soybean oil, poppyseed oil, a 3:1 lard-corn oil mixture, and sunflower seed oil. Based upon its review of these studies, the agency believes that the results reported in Ref. 14 may not represent a reproducible effect. However, even if LEAR oil does have an effect on cardiac phospholipid content, the agency does not have any information that would relate that effect to a potential health hazard.

In Ref. 14, differences were also observed between the fatty acid composition of the cardiac lipids of those rats fed LEAR oil as compared to the cardiac lipids of rats fed 15 percent sunflower seed oil. The agency notes that it is well established that the fatty acid composition of tissue lipids generally reflects the composition of ingested fatty acids. The agency believes that because there is a noticeable difference in the fatty acid composition of LEAR oil as compared to that of sunflower seed oil, a difference in the fatty acid composition of the cardiac lipids of rats fed LEAR oil compared to that of rats fed sunflower seed oil would be expected. FDA consequently does not consider the observed differences in the fatty acid composition of cardiac lipids to be an adverse health effect.

Therefore, this comment does not provide any basis upon which to conclude that the effects observed in Ref. 14 establish that ingestion of LEAR oil is unsafe.

3. The same comment indicated that LEAR oil may be associated with increased mortality of rats under cold stress (Ref. 21), a significant change in heart fat content in chickens (Ref. 22), and problems with energy utilization in

chicks (Ref. 23) and humans (Refs. 24 and 25).

A. Cold Stress Mortality

FDA has reviewed Ref. 21, cited by the comment as associating LEAR oil with increased mortality of rats under cold stress. The agency finds that the rapeseed oil used in this study contained 6.5 percent erucic acid and thus was not a LEAR oil. Furthermore, the cold stress mortality of animals fed the rapeseed oil was less than the mortality of animals fed peanut oil as the control. The agency is not aware of any study that has reported on the cold stress mortality of rats fed LEAR oil. FDA consequently concludes that there is no basis on which to find that ingestion of LEAR oil causes increased mortality of rats under cold stress.

B. Change in Heart Fat Content

FDA has evaluated Ref. 22, which the comment claims establishes that LEAR oil causes changes in the heart fat content of chicks. The authors of this study state that there is no greater lipid accumulation in the heart tissues of chicks fed LEAR oil than in the heart tissues of chicks fed soybean oil. FDA therefore finds that this reference does not support the comment's assertion with respect to the heart fat content of chicks.

The comment might have misinterpreted the study. There was a change in the fatty acid composition of the heart lipids of chicks fed LEAR oil. However, as explained in response to paragraph 2 above, the fatty acid composition of tissue lipids generally reflects the composition of fatty acids present in the diet. Thus, the change that occurred in the fatty acid composition of cardiac lipids merely reflects the fatty acid composition of LEAR oil and does not establish that this substance represents a potential health hazard.

C. Energy Utilization

The agency has also reviewed the references cited by the comment to support its claim that LEAR oil is associated with poor energy utilization in chicks (Ref. 23) and in humans (Refs. 24 and 25). Ref. 23 reveals that rapeseed oil containing 2.5 percent erucic acid is not as well utilized by chicks as is sunflower seed oil. However, this rapeseed oil is not a LEAR oil because it contains more than 2 percent erucic acid.

The agency is also aware of two studies that show no reduction in energy utilization when LEAR oil is fed to chicks. In the first study (Ref. 26), no reduction in feed efficiency was observed in chicks fed two different LEAR oils when compared to chicks fed soybean oil. In the other study (Ref. 22), a LEAR oil produced a growth response in chicks similar to that produced by soybean oil. FDA therefore concludes on the basis of these studies that LEAR oil is not poorly utilized as a source of energy by the chick.

As for the comment's claims with respect to humans, the authors of Ref. 24 state that there was no significant difference between two different LEAR oils and soybean oil in energy utilization in humans. The other study mentioned by the comment (Ref. 25) does show a decrease in energy utilization in humans, but the rapeseed oil used in that study contained 47 percent erucic acid. That study does not investigate whether such a decrease exists for LEAR oil. The agency therefore concludes that the comment has not presented any evidence of a problem with energy utilization of LEAR oil by humans.

4. The same comment cited several studies that it claimed support the finding that high erucic acid rapeseed oil is associated with greater mortality under cold stress in rats (Refs. 21 and 45), with increased fat deposition in heart muscle of rats (Refs. 6 and 46 through 51), with increased fat deposition in heart muscle of monkeys (Ref. 52), with cardiac muscle degeneration and necrosis in rats (Refs. 4, 5, 12, 50, and 53 through 57), with decreased weight gain in chicks (Ref. 23), and with decreased weight gain in rats (Refs. 22 and 57).

FDA has reviewed these and other literature references on the toxic effects of high erucic acid rapeseed oil in experimental animals. The agency acknowledges that high levels of erucic acid produced adverse effects in these studies and considers that these studies are useful in identifying the target organs and principal pathological effects that are attributable to high dietary ingestion of erucic acid. However, these effects were observed only when the exposure to erucic acid was at levels that greatly exceed the expected human exposure from the use of LEAR oil of 10 milligrams erucic acid per kilogram body weight (as discussed in section III, *supra*). In the references cited in this comment, the high erucic acid rapeseed oils contained 20 to 50 percent erucic acid and were consumed by the animals at levels in the range of 15 to 20 percent of their total diet. The agency's review of the studies with LEAR oil refutes any suggestion that that substance produces the adverse effects seen in the studies of high erucic acid rapeseed oils. Nevertheless, the agency has evaluated the references cited by this comment.

A. Cold Stress Mortality

The issue of whether consumption of LEAR oil leads to greater mortality under cold stress in rats has been discussed in paragraph 3. Although Ref. 45 is not discussed in paragraph 3, it is a study on a rapeseed oil containing 37 percent erucic acid and thus provides no basis for the agency to change the conclusion that it states in paragraph 3.

B. Myocardial Lipidosis

The agency agrees with the comment that Refs. 6, 46, 47, 48, 49, 50, and 51 confirm that rats fed high erucic acid rapeseed oil show evidence of myocardial lipidosis. However, in three of these studies (Refs. 6, 47, and 49), the rats that were fed LEAR oil did not develop myocardial lipidosis. Moreover, FDA finds on the basis of a comprehensive 2-year feeding study with LEAR oil (Ref. 18), that the incidence and severity of myocardial lipidosis in rats fed LEAR oil are similar to the incidence and severity of this problem in rats fed partially hydrogenated soybean oil. The agency believes that Refs. 6, 18, 47, and 49 provide evidence to refute the suggestion from the studies with high erucic acid rapeseed oil that LEAR oil is associated with myocardial lipidosis in rats to a greater degree than other vegetable oils.

With respect to myocardial lipidosis in monkeys, although Ref. 52 shows a positive effect in animals fed high erucic acid rapeseed oil, a similar result, yet less severe, was also found in animals fed a mixture of lard and corn oil in the same study. Moreover, in Ref. 20, in which LEAR oil was fed to monkeys for up to 24 weeks, histochemical studies revealed that although there was a slow increase in erucic acid levels in the cardiac lipids, there was no increase in overall lipid content of cardiac tissue observed in the LEAR oil group. FDA therefore concludes that, in monkeys, the ingestion of LEAR oil does not cause myocardial lipidosis.

C. Myocardial Necrosis

The agency agrees with the comment that the references cited provide evidence that high erucic acid rapeseed oil produces myocardial necrosis in rats. However, FDA believes that the results of the 2-year feeding study with LEAR oil (Ref. 18) has an important bearing on the significance of these findings. This study reported no myocardial necrosis as such in rats fed LEAR oil. Although chronic myocarditis and interstitial fibrosis were found in rats fed LEAR oil, the incidence of these findings was comparable in the LEAR oil-fed and

control (partially hydrogenated soybean oil) rats. In addition, histopathological examination of cardiac tissue from a 24-week feeding study with monkeys (Ref. 20) did not reveal any myocardial damage associated with LEAR oil. Consequently, FDA believes that Refs. 18 and 20 provide evidence that consumption of LEAR oil does not induce myocardial necrosis.

D. Energy Utilization

FDA has addressed the issue of whether consumption of LEAR oil leads to a reduction in energy utilization in chicks in paragraph 3. This comment cited Refs. 22 and 57 in support of its claim that high erucic acid rapeseed oil is associated with a decreased weight gain in rats.

FDA finds that Ref. 22 is a study in chicks, not in rats. This study was discussed in paragraph 3 above. Although the study indicated a reduced growth rate in chicks fed high erucic acid rapeseed oil, the significance of this finding is offset by the fact that the same study demonstrated that there is no difference in growth between chicks fed LEAR oil and chicks fed soybean oil.

Ref. 57 is a study of synthetic oils containing *cis* or *trans* isomers of octadecenoic acid or docosenoic acids. This study is irrelevant to the safety of LEAR oil because the amount of *cis*-docosenoic acid (erucic acid) added to the diet of the rats was equivalent to rapeseed oil containing 38 percent erucic acid. Thus, the agency finds that this comment does not establish that LEAR oil is associated with decreased weight gain in chicks and rats.

5. One comment submitted 10 literature references (Refs. 4, 14, and 26 through 33) and claimed that these references establish that undesirable effects are caused by the ingestion of LEAR oil. The comment was not specific regarding the effects claimed but requested that FDA review the studies before approving LEAR oil for human food use.

FDA finds that five of these references (Refs. 4, 28 through 30, and 32) were either contained in the petition or were reviewed by the agency during its own search of the literature on LEAR oil. FDA has reevaluated these references. FDA discussed Ref. 4 in paragraph 1. Refs. 29 and 32 used male Sprague-Dawley rats fed LEAR and other vegetable oils for a period of up to 16 weeks. These studies indicate that the incidence of cardiac lesions in Sprague-Dawley rats is higher with LEAR oil than with other vegetable oils. The agency has discussed its conclusion that this result is not of toxicological significance for humans in paragraph 1.

Ref. 30 used male Wistar rats that were fed LEAR and other vegetable oils for a period of 25 weeks. The myocardial necrosis among animals fed LEAR oil was comparable to that found in rats fed soybean oil. Ref. 28 describes a study in which pigs were fed diets containing soybean oil or LEAR oil for periods of up to 16 weeks. The incidence of cardiac lesions was comparable between the LEAR and soybean oil groups. FDA therefore does not consider these five references to show any specific deleterious effect from the consumption of LEAR oil that relates to human safety.

Ref. 14 indicates that in male Sprague-Dawley rats there are effects on the incidence of cardiac lesions and cardiac lipids when these animals are fed LEAR oil. As discussed in paragraphs 1 and 2, however, FDA has concluded that these findings are not significant for humans. FDA has also found, as discussed in paragraph 3, that Ref. 26 does not report an adverse effect from the ingestion of LEAR oil. The agency finds that the remaining three references (Refs. 27, 31, and 33) also do not raise any significant questions about the safety of LEAR oil.

Ref. 31 is a study of changes in the myocardial ultrastructure of rats fed diets that were 20 percent oil. The oils tested included LEAR oil, corn oil, and two high erucic acid rapeseed oils (3.6 and 38.9 percent erucic acid). The authors noted that compared with rats fed corn oil, rats fed high erucic acid rapeseed oil had more lipid droplets and more frequently had mitochondria alterations. However, only a small increase in lipid droplets and small changes in the myocardial ultrastructure were observed in rats fed LEAR oil as compared to the rats fed corn oil.

The agency is aware of an additional study whose authors reported no difference in the frequency of lipid droplets in rats fed LEAR oil as compared to rats fed soybean oil (Ref. 39). The authors of this study (Ref. 39) relate the occurrence of lipid droplets among both the soybean and LEAR oil groups to the polyunsaturated fatty acid content of these oils.

In addition, Ref. 11 reported the results of comparisons of the myocardial ultrastructure of rats fed LEAR oil for periods of up to 1 year with that of rats fed peanut oil for periods of up to 1 year. The authors of this reference reported that the incidence of myocardial alterations was comparable in the two groups.

Based on the results of Refs. 31 and 39, the agency concludes that the occurrence of lipid droplets is directly related to the polyunsaturated fatty acid content of the oils the animals were fed. Corn oil has less polyunsaturates than either soybean oil or LEAR oil and thus produced less lipid droplets. Because soybean oil and LEAR oil contain comparable levels of polyunsaturates, they produced comparable levels of lipid droplets. Based on the results of Ref. 11, FDA finds that compared to peanut oil, LEAR oil does not cause a significant increase in myocardial alterations. Thus, LEAR oil is no different from other vegetable oils with regard to its effect on the myocardial ultrastructure.

For these reasons, FDA finds that the results of Ref. 31 do not indicate a potential adverse health effect for LEAR oil.

Ref. 33 is a study of the effects of choline, inositol, methionine, and magnesium on the incidence of myocardial lesions in Sprague-Dawley rats fed 20 persent oil rich diets. The authors found that adding choline, inositol, methionine, and magnesium to purified rat diets decreased significantly the occurrence of lesions in rats fed soybean oil, LEAR oil, and high erucic acid rapeseed oil. However, the primary purpose of this study was to investigate the effect of nonfat essential nutrients on the incidence of cardiac lesions in rats fed high oil diets and not to evaluate the safety of LEAR oil. Indeed, the authors concluded that "essential nutrient adequacy of purified diets typically utilized in evaluating the incidence of 'dietary fat-induced' lesions may be a more significant factor in the etiology of these cardiopathogenic changes than is the fatty acid composition of the dietary oil." At any rate, as discussed earlier, LEAR oil caused no increase in cardiac lesions in a 2-year rat study (Ref. 18), when compared to a partially hydrogenated soybean oil control. The agency, therefore, disagrees with the comment that Ref. 33 indicates a potential undesirable effect from human consumption of LEAR oil.

The agency has also reviewed Ref. 27, which the comment cites in support of its claim that LEAR oil causes alterations in the liver structure of pigs. The agency finds that although alterations in the liver ultrastructure were observed in this study with LEAR oil, alteration were also found in this study in the liver ultrastructure of pigs fed soybean and herring oils. The agency notes that the authors of the study concluded that the alterations represent functional modifications of metabolism in the liver cell in response to the large amount of oil in the diet.

Furthermore, although the differences found in the liver ultrastructure were distinctive for each of the three types of oils studied, the authors do not attribute

these differences to a toxic effect of LEAR oil or of any of the other oils studied. Based upon its review of this study, the agency concludes that the study does not raise a significant question regarding the safety of LEAR oil. FDA, therefore, disagrees with the comment that potential adverse effects may be attributed to LEAR oil on the basis of Ref. 27.

Thus none of the references cited in this comment present any reason to believe that use of LEAR oil is unsafe.

6. One comment submitted 10 literature references (Refs. 4, 14, 15, 26, 27, 29, 30, 33, 34, and 35) and suggested that "diverse metabolic effects" may be associated with the consumption of LEAR oil by rats, poultry, swine, and monkeys in these studies. The comment also stated that these studies suggest that factors other than erucic acid may be responsible for these metabolic effects. The comment specifically cited Ref. 27 as evidence that effects from LEAR oil are not only associated with the heart but may also be associated with alterations in liver structure in pigs. The comment requested that FDA review these studies closely before approving LEAR oil for human food use.

Although the comment did not state specifically the type of "diverse metabolic effects" that may be associated with the consumption of LEAR oil from these animal studies, FDA has reviewed the studies and has considered any potential adverse health effects that were indicated by the studies.

Four of the studies (Refs. 4, 29, 30, and 34) cited in this comment were either included in the petition or were reviewed by the agency during its initial search of the literature on LEAR oil. The agency has discussed eight of the references cited in the comment (Refs. 4, 14, 15, 26, 27, 29, 30, and 33) in response to the comments discussed above. FDA has evaluated all of the references cited in this comment and finds that they do not establish any specific adverse metabolic effect arising from the consumption of LEAR oil, as compared to the consumption of other vegetable oils, by rats, poultry, swine, and monkeys.

In addition to the references already discussed, the agency has reviewed Refs. 34 and 35. Ref. 34 is a study in which male and female monkeys were fed diets containing either soybean oil or LEAR oil (the oil being 20 percent of the diet) for up to 24 weeks. Cardiac histopathology, electrocardiograms, and clinical chemical results (e.g., SGOT, CPK, LDH, and d-HBDH) did not indicate any adverse effects from the LEAR oil diet on cardiac function. In addition, no adverse effect on blood coagulation from consumption of LEAR oil was found. There were no significant differences between the diet groups in the relative weights of heart, liver, and thyroid. However, among animals on the LEAR oil diet, females had increased adrenal weights, and males had decreased kidney weights, as compared to the soybean oil group. The authors stated that the biological significance of these differences is not known. FDA agrees with the authors and considers that these differences need to be validated before being considered as a physiological effect of LEAR oil. Because only a few animals were used in each group, it is not certain how reproducible these effects are, and it is also not clear which group had organ weights that were consistent with the normal range of organ weight values and which group deviated from the normal range. FDA therefore concludes that this study does not provide any evidence upon which to conclude that the consumption of LEAR oil is unsafe.

Ref. 35 is an unpublished rat feeding study. The results of this study have been published in Ref. 17 by the same author. Ref. 17 provides more detail about this study than Ref. 35. Consequently, FDA also reviewed Ref. 17. There are two sets of experiments reported in Ref. 17. The first used rapeseed oil containing 2.5 percent erucic acid, and the second used a LEAR oil containing 1.5 percent erucic acid. Only the second set of experiments bears directly on the issue of the safety of LEAR oil.

In that set of experiments, individual groups of rats were fed oleic acid (as a control fatty acid), erucic acid, cetoleic acid, or LEAR oil in their diets for a similar short (6 day) feeding regime. The fatty acids (oleic acid, cetoleic acid, and erucic acid) were supplemented with a mixture of sunflower seed oil and lard, while the LEAR oil was given with and without a supplement of sunflower seed oil. Cetoleic acid is not found in vegetable oil and thus is not relevant to the safety of LEAR oil. Consequently, FDA will not discuss that fatty acid here.

The incidences of heart lesions with the oleic acid, LEAR oil, and erucic acid groups were 15 percent, 20 percent, and 100 percent, respectively. The number of heart lesions per group with the oleic acid, LEAR oil, and erucic acid groups were 0.1, 10, and 223, respectively. Furthermore, when half of the LEAR oil was replaced with sunflower seed oil, the incidence of heart lesions increased from 20 percent to 45 percent and the number of heart lesions per group increased from 10 to 28.

FDA finds that the methodolgy used in this study, which involved only 6 days of study, has not been confirmed by other investigators. Assuming that the methology is reliable, the number of rats affected by heart lesions in the oleic acid and LEAR oil groups appears to be similar (2 to 4 rats out of 20). However, the incidence of heart lesions per affected animal is significantly higher in the LEAR oil group. FDA considers that oleic acid alone is not reflective of any vegetable oil, and that it is not a reasonable control for LEAR oil. Furthermore, the authors suggest that this increased incidence of heart lesions per affected animal may be related in part to the polyunsaturated fatty acids (e.g., linoleic acid) in LEAR oil, rather than to erucic acid alone. This explanation is supported by the fact that LEAR oil supplemented by sunflower seed oil (a rich source of polyunsaturates) produced a higher incidence and severity of heart lesions than LEAR oil alone.

Moreover, Ref. 17 provides a basis upon which to compare the safety of LEAR oil with that of sunflower seed oil. The rats fed a mixture in which half of the LEAR oil was replaced with sunflower seed oil had more than twice as many heart lesions, and had more severe heart lesions, than rats fed LEAR oil alone. Based on the results of this study, the agency concludes that sunflower seed oil caused both the number and severity of lesions to increase markedly, and that LEAR oil is no more likely to cause cardiac lesions than sunflower seed oil.

Based on the foregoing, the agency disagrees with the comment's claim that Ref. 35 indicates that adverse health effects may be associated with LEAR oil.

The agency thus finds no basis in any of the references cited by this comment to question the safety of LEAR oil or to suggest that factors other than erucic acid and polyunsaturated fatty acids are responsible for any adverse health effects associated with rapeseed oil.

7. One comment disagreed with the statement in the petition that the rat is an inappropriate model for the study of vegetable oils. The comment also asserted that the petition is inadequate because it rests upon studies of short duration and does not provide data on chronic exposure, reproduction, or teratology for LEAR oil. The comment submitted a draft report of a recently conducted 2-year feeding study of LEAR oil, partially hydrogenated soybean oil, and partially hydrogenated fish oil in the rat (Ref. 18).

FDA recognizes that rats, particularly the Sprague-Dawley rat, compared to mice (Ref. 3), pigs (Ref. 19), or monkeys (Refs. 20 and 34), are unusually susceptible to heart lesions when fed vegetable oils, and that rats are also more susceptible to cardiac lesions as the degree of unsaturation of various vegetable oils increases (Ref. 38). The agency also recognizes that in some studies, Sprague-Dawley rats fed LEAR oil have had a higher incidence and severity of myocardial lesions than those rats fed other vetegable oils. However, in other strains of rats, such as the Wistar rat, there were no significant differences in the number and severity of myocardial lesions suffered by those rats fed LEAR oil as compared to those rats fed other vegetable oils (Refs. 2, 3, and 18).

FDA believes that studies involving rats are useful in assessing the safety of LEAR and other vegetable oils for two reasons: (1) The great sensitivity of rats to vegetable oils ensures that tests with these animals will reveal toxic effects from these substances that may otherwise not be detected in tests with other animal species, and (2) the rat is the most accessible and economic animal species in toxicological laboratories. FDA therefore finds that it is appropriate to consider all studies, including those involving rats, that relate to the potential toxicity of LEAR oil.

The agency recognizes that the petition does not contain chronic, reproduction, or teratology studies for LEAR Oil. FDA believes that these types of studies are not necessary to evaluate the safety of LEAR oil because the composition of this oil, except for its erucic acid content, is similar to other vegetable oils. In addition, there are human and extensive animal studies in the petition that indicate that this oil's nutritional and toxicological profile is similar to those of other vegetable oils.

The agency also finds that the nutritional deficiencies and cardiotoxicity associated with high erucic acid rapeseed oil have been observed in studies of relatively short duration, and that therefore these effects may be evaluated for LEAR oil in studies conducted for a similar period of time. This finding is supported by data in the petition (e.g., Ref. 3) that demonstrate that a 4-month period is appropriate for the study of maximum heart lesion development in the rat, and by the fact that studies extended for up to 1 year in the rat do not produce significantly different results. FDA therefore believes that the studies contained in the petition, which were conducted for either 6 months or 1 year in rats (Refs. 2, 3, 8, 10, 11, and 36), are of sufficient duration to evaluate the potential health effects of LEAR oil.

Furthermore, FDA has evaluated the study (Ref. 18) submitted by the comment. The study is a 2-year feeding study, with in utero exposure, in which Wistar rats were fed high levels of either LEAR (1.2 percent erucic acid) or partially hydrogenated soybean oil. (FDA did not evaluate the data for partially hydrogenated fish oil because this oil is not approved for food use in the United States.) Although the study indicates that the severity of cardiac lipidosis was slightly greater in the LEAR oil group than in the partially hydrogenated soybean oil group at 4 days and 26 weeks, no differences were observed in the incidence of cardiac lipidosis at these time intervals, nor were there any significant differences in the reported incidence of chronic myocarditis/interstitial fibrosis for the life-span phase of the feeding study.

Based upon its review of this study, the agency concludes that the slightly greater severity of cardiac lipidosis observed in the animals fed LEAR oil in comparison to the animals fed partially hydrogenated soybean oil can be attributed to the degree of saturation of the soybean oil utilized in this study. Increases in the levels of saturated fatty acids are associated with a lower incidence of heart lesions (Refs. 13 and 38). Also, the reproductive data obtained from the in utero phase of this study did not indicate any marked differences between LEAR and soybean oils. The agency, therefore, concludes that this study does not demonstrate any toxicity from LEAR oil use that would require limitation of its use for human consumption.

8. One of the comments stated that erucic acid is a toxic fatty acid and is not essential for human nutrition. The comment further expressed the opinion that, because the effects of LEAR oil on human nutrition are unknown, and because research data from animal studies on LEAR oil are uncertain, additional research is warranted.

The agency finds that erucic acid is not toxic when it is a component of LEAR oil at a level of no more than 2 percent of the fatty acids. Data in the petition indicate that erucic acid is metabolized by mammals (Ref. 59), albeit less rapidly than some fatty acids, and that it is synthesized in some mammalian species (Refs. 60, 61, and 62). Additionally, numerous animal and human studies contained in the petition also demonstrate that LEAR oil containing up to 2 percent erucic acid is as safe as other vegetable oils for human consumption.

Although erucic acid is not an essential fatty acid, the agency is aware that many other fatty acid components of vegetable oils, such as stearic acid and oleic acid, also are not essential for human nutrition. The agency therefore considers the fact that erucic acid is not essential is not a safety issue when considering whether LEAR oil containing a small amount of erucic acid can be safely consumed by humans.

The agency also concludes that the nutritional and physiological properties of LEAR oil in humans have been adequately studied (Ref. 24 and 37), and that research data available in the petition demonstrate that LEAR oil that contains 2 percent or less erucic acid is safe. FDA therefore does not believe it necessary to require additional research to support the safety of LEAR oil.

9. One of the comments claimed that the effects attributed to erucic acid have not been proven to be true, and thus that reducing the content of erucic acid in rapeseed oil will not make the oil safer for human consumption. The comment further asserted that isomers of erucic acid, such as cetoleic acid in marine oil, have never been shown to have the type of adverse effects dealt with by the petition.

The agency finds this comment to be without merit. The petition contains sufficient data to demonstrate clearly that significantly fewer cardiac lesions were found in animals fed LEAR oil than in animals fed rapeseed oils containing higher levels of erucic acid. The agency is confident that this difference in the occurrence of lesions is not caused by an unknown component. Refs. 29 and 32 compare the cardiotoxicity of LEAR oil, rapeseed oil, and other vegetable oils with the cardiotoxicity of the purified triglyceride fraction (including the erucic acid component) of these oils. These studies revealed that the purified triglyceride fractions were as cardiotoxic as the oils as a whole.

On the basis of this evidence, it is clear that the observed cardiotoxicity is the result of the triglyceride fraction and not of some unknown component. Therefore, FDA concludes that reducing the erucic acid content will reduce the toxicity of the oil.

Cetoleic acid is not present in LEAR oil. FDA thus concludes that a review of the safety of cetoleic acid is not relevant to a determination on the safety of LEAR oil.

10. One of the comments stated that GRAS substances may not be subjected to any limitations under the law. The comment asserted that because LEAR

oil would require a limitation on its use or human consumption, it should not be accorded GRAS status. The comment also stated that LEAR oil does not meet the GRAS criteria because it has no history of common use in food before January 1, 1958. The comment thus suggested that FDA should review LEAR oil as a food additive for which a tolerance level should be set.

FDA finds that the comment is incorrect in its assertion that substances may only be affirmed as GRAS based upon a history of use in food. A substance may be eligible for GRAS status based upon an evaluation of its safety under either (1) a history of common use in food prior to January 1, 1958, or (2) scientific procedures. Because LEAR oil has no history of common use in food prior to January 1, 1958, FDA evaluated the GRAS status of its use based on scientific procedures.

The comment is also incorrect in its assertion that GRAS substances may not be subjected to any limitations. FDA may establish limitations on ingredients by adopting specifications for the substances or by adopting specific limitations on their conditions of use under § 184.1(b)(2) (21 CFR 184.1(b)(2)). In this case, FDA has evaluated the safety of LEAR oil and, to reflect that evaluation, is imposing a 2 percent maximum level of erucic acid based on the total fatty acid content of the oil as a limitation in the food-grade specifications for LEAR oil.

Partially Hydrogenated LEAR Oil

11. The agency has also considered the safety of partially hydrogenated LEAR oil. Ref. 13, for example, reveals that partial hydrogenation of LEAR oil results in comparable or lower cardiac toxicity than unhydrogenated LEAR oil. The agency therefore concludes on the basis of this and other published studies that the use of partially hydrogenated LEAR oil is safe.

Infant Formula Use of LEAR Oil

12. The petitioner submitted information to support its request that FDA affirm as GRAS the use of LEAR oil in infant formulas. However, the petitioner subsequently requested that FDA not evaluate this use of LEAR oil until the Canadian government completes its own review of the properties of various food oils used in infant formulas. Therefore, FDA is not affirming this use of Lear oil as GRAS.

To make its intent clear, the agency is affirming as GRAS the use of LEAR oil and of partially hydrogenated LEAR oil in food, except in infant formulas. The agency will review this use at a later date if a new GRAS affirmation petition is submitted.

V. Conclusion

In summary, FDA, having evaluated all information in the petition, other relevant information that it found in its own search of the scientific literature, and information submitted in the comments addressed above, concludes as follows:

1. In its notice of filing for the Canadian petition, FDA defined LEAR oil as rapeseed oil containing no more than 2 percent erucic acid based on its total fatty acid content.
2. The comments on the notice of filing did not present any evidence that provides a basis upon which to question the safety of LEAR oil. Some of the comments, in fact, provide additional information supporting that the use of this substance is safe.
3. LEAR oil is safe for human consumption as a fat or an oil in food when used in accordance with current good manufacturing practice.
4. LEAR oil cannot be affirmed as GRAS based on a history of common use in food prior to January 1, 1958.
5. LEAR oil can be affirmed as GRAS based on scientific procedures, because a large body of scientific data establishing that the use of this substance in food is safe has been published in the scientific literature.
6. Partially hydrogenated LEAR oil can also be affirmed as GRAS based on scientific procedures for use as a fat or an oil in food.

Specifications

Although food standards developed by Canada and the World Health Organization's Codex Alimentarius Commission exist for rapeseed oil, the agency has chosen to work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specification for LEAR oil. If acceptable specifications are developed, the agency will incorporate them into this regulation. Until specifications are developed, FDA has determined that the public health will be adequately protected if LEAR oil complies with the description in this regulation and is of food-grade purity (21 CFR 182.1(b)(3) and 170.30(h)(1)).

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 may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Regulatory Flexibility Act

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this final rule would have on small entities including small businesses and has determined that the effect of this final rule is to make LEAR oil available for human consumption. 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.

Executive Order 12291

In accordance with Executive Order 12291, FDA has examined the economic effects of this rule. Although this action will create more diversity in the food oil marketplace, the agency has determined that it is not a major rule as defined by the Order.

VI. References

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List of Subjects in 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), Part 184 is amended in § 184.1555 by adding new paragraph (c), to read as follows:

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

§ 184.1555 Rapeseed oil.

* * * * *

(c) *Low erucic acid rapeseed oil.* (1) Low erucic acid rapeseed oil is the fully refined, bleached, and deodorized edible oil obtained from certain varieties of *Brassica napus* or *B. campestris* of the family *Cruciferae*. The plant varieties are those producing oil-bearing seeds with a low erucic acid content. Chemically, low erucic acid rapeseed oil is a mixture of triglycerides, composed of both saturated and unsaturated fatty acids, with an erucic acid content of no more than 2 percent of the component fatty acids.

(2) Low erucic acid rapeseed oil as defined in paragraph (c)(1) of this section may be partially hydrogenated to reduce the proportion of unsaturated fatty acids. When the partially hydrogenated low erucic acid rapeseed oil is used, it shall be referred to as partially hydrogenated low erucic acid rapeseed oil.

(3) In addition to limiting the content of erucic acid to a level not exceeding 2 percent of the component fatty acids, FDA is developing other food-grade specifications for low erucic acid rapeseed oil and partially hydrogenated low erucic acid rapeseed oil in cooperation with the National Academy of Sciences. In the interim, the ingredients must be of a purity suitable for their intended use.

(4) Low erucic acid rapeseed oil and partially hydrogenated low erucic acid rapeseed oil are used as edible fats and oils in food, except in infant formula, at levels not to exceed current good manufacturing practice.

Effective date. This regulation shall become effective January 28, 1985.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)).)

Dated: January 9, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

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