

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (e) of this AD to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

Note 2: This AD references certain Learjet service bulletins for applicability information, and inspection and replacement procedures. This AD requires performing certain follow-on actions repetitively, although the service bulletins specify accomplishing these actions just once. Where there are differences between the AD and the service bulletins, the AD prevails.

To prevent imbalance of the fuel loads in the wings of the airplane, which can significantly reduce lateral control of the airplane, accomplish the following:

(a) Within 50 hours time-in-service after the effective date of this AD or prior to the accumulation of 600 hours time-in-service since installation of the flapper valve, whichever occurs later: Perform an inspection to detect deterioration (such as cracks, cuts, breaks, splits, or warpage) of both flapper valves of the tip tank in each wing, in accordance with either Learjet Service Bulletin SB 23/24/25-28-2, dated October 6, 1995 (for Model 23, 24, and 25 airplanes), or Learjet Service Bulletin SB 35/36-28-10, dated October 6, 1995 (for Model 35 and 36 airplanes); as applicable. Repeat this inspection thereafter at intervals not to exceed 600 hours time-in-service.

(1) If no deterioration of the flapper valve is detected, prior to further flight, inspect the flapper valve to ensure proper positioning, inspect the condition of the screws that retain the flapper valve to the plate assembly to ensure that the flapper valve is secure, inspect to ensure that the flapper valve completely covers the opening of the tube and is seated against the tube, and inspect the flapper valve to verify that it moves freely; and accomplish the follow-on corrective actions, if any discrepancy is found. These actions shall be accomplished in accordance with the applicable service bulletin.

(2) If any flapper valve is found to be deteriorated, prior to further flight, replace it with a new flapper valve in accordance with the applicable service bulletin.

(b) Except as provided in paragraph (c) of this AD, at the later of the times specified in paragraphs (b)(1) and (b)(2) of this AD: Replace both flapper valves of the tip tank in

each wing with new flapper valves in accordance with either Learjet Service Bulletin SB 23/24/25-28-2, dated October 6, 1995 (for Model 23, 24, and 25 airplanes), or Learjet Service Bulletin SB 35/36-28-10, dated October 6, 1995 (for Model 35 and 36 airplanes); as applicable.

(1) Within 5 years since date of installation of the flapper valve, or prior to the accumulation of 2,400 total hours time-in-service on the flapper valve, whichever occurs earlier.

(2) Within 50 hours time-in-service after the effective date of this AD.

(c) For airplanes on which the age and time-in-service of the flapper valve cannot be determined: Within 50 hours time-in-service after the effective date of this AD, replace both flapper valves of the tip tank in each wing in accordance with either Learjet Service Bulletin SB 23/24/25-28-2, dated October 6, 1995 (for Model 23, 24, and 25 airplanes), or Learjet Service Bulletin SB 35/36-28-10, dated October 6, 1995 (for Model 35 and 36 airplanes); as applicable.

(d) Within 600 hours time-in-service following replacement of any flapper valve in accordance with the requirements of this AD, and thereafter at intervals not to exceed 600 hours time-in-service: Accomplish the requirements of paragraph (a) of this AD.

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Wichita Aircraft Certification Office (ACO), FAA, Small Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita ACO.

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(g) The actions shall be done in accordance with either Learjet Service Bulletin SB 23/24/25-28-2, dated October 6, 1995; or Learjet Service Bulletin SB 35/36-28-10, dated October 6, 1995; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Learjet, Inc., One Learjet Way, Wichita, Kansas 67209-2942. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Wichita Aircraft Certification Office, Small Airplane Directorate, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on December 27, 1995.

Issued in Renton, Washington, on November 27, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95-29300 Filed 12-11-95; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 88G-0318]

Glyceryl Palmitostearate; Affirmation of GRAS Status of Direct Food Substance

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that glyceryl palmitostearate is generally recognized as safe (GRAS) for use as a formulation aid in excipient mixtures used in tablets. This action is in response to a petition filed on behalf of Gattefossé, S.A.

EFFECTIVE DATE: December 12, 1995.

FOR FURTHER INFORMATION CONTACT: Dennis M. Keefe, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3090.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory History

In accordance with the procedures described in 21 CFR 170.35, a petition was submitted (GRASP 8G0344) on behalf of Gattefossé, S.A., 36 Chemin de Genas, Saint Priest, France, requesting that glyceryl palmitostearate be affirmed as GRAS for use as an excipient in tablets.

FDA published a notice of filing of this petition in the Federal Register of October 20, 1988 (53 FR 41241), and gave interested parties an opportunity to submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. FDA received no comments in response to that notice.

B. Standards for GRAS Affirmation

Under § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and

experience to evaluate the safety of food substances. The basis of such views may be either scientific procedures, or in the case of a substance used in food before January 1, 1958, through experience based on common use in food. General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation, and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)).

The subject petition relies on scientific procedures evidence to support GRAS affirmation of glyceryl palmitostearate as an excipient in tablets.

C. Manufacturing Process and Identity

According to information contained in the petition, glyceryl palmitostearate is manufactured by heating a mixture of glycerin (glycerol) and a mixture of fatty acids of vegetable origin composed of roughly equal amounts (48 to 50 percent) of palmitic and stearic acid, and 4 percent myristic acid.

Glyceryl palmitostearate prepared in this way is a mixture of mono-, di-, and triglycerides of palmitic and stearic acids. It contains primarily di- and triglycerides (>78.5 percent), a small amount of monoglycerides (8 to 17 percent), and trace amounts of free glycerin (<1.0 percent) and free palmitic and stearic acid moieties (<3.0 percent).

D. Use and Exposure

The proposed use of the substance is as a lubricating agent in excipient mixtures for preparation of tablets (vitamin and related products). The technical properties of the substance in excipient formulations are similar to those of other fatty acid glycerides. The petitioner asserts that the normal use level of the substance will be 6 to 40 percent of the total tablet weight and that the 40 percent level is typical for long-duration timed-release formulations. The petitioner also estimates that although the typical dosage is approximately two tablets per day, some individuals may take as many as six tablets per day.

Based on a typical dose of two 600-milligram (mg) tablets per person per day, FDA estimates that the typical intake of glyceryl palmitostearate would be from 72 to 480 mg per person per day (Ref. 2). The petitioner estimates that on the basis of 2,000 to 2,700 calories per person per day total food intake and 35 percent fat in the diet (one-third of all ingested fat being fully saturated), the

intake of saturated fat per person per day is between 20 and 30 grams. This estimate is consistent with dietary data compiled by the United States Department of Agriculture (1985). Based on this information, FDA concludes that the proposed use of glyceryl palmitostearate will increase the dietary intake of saturated fat by 2.4 percent per person per day (Ref. 2).

II. Safety

The notice of filing in this proceeding used the name "glyceryl palmitostearate" to represent the substance that is the subject of the petition. The agency considers this name to be appropriate, although the substance is actually not a single chemical entity, but rather a mixture of di- and triglycerides with a small amount of monoglycerides.

Triglycerides (triacylglycerols) are the most abundant form of fat in the human diet (Ref. 1). Their component fatty acids are the major energy reserve of plant and animal cells (Ref. 1). When ingested, triglycerides are initially digested into free fatty acids and diglycerides. Diglycerides are further digested into a mixture of monoglycerides, glycerol, and free fatty acids. Monoglycerides, glycerol, and free fatty acids are the chemical forms in which dietary fats are absorbed into the body (Ref. 1). Thus, all of the components of glyceryl palmitostearate are present as components of fats found in foods or are generated in large amounts in the human digestive tract during the digestion of fat (Ref. 1). As previously stated, the proposed use of glyceryl palmitostearate will not result in a material increase in exposure to these substances (Ref. 2).

The agency has previously examined the safety of the components of glyceryl palmitostearate. Glycerin is listed as a multipurpose GRAS substance in 21 CFR 182.1320. Mono- and diglycerides prepared from fats, oils, or fat-forming acids derived from edible sources, including palmitic and stearic acids, are affirmed as GRAS in 21 CFR 184.1505. Stearic and palmitic acid are approved as multipurpose food additives in 21 CFR 172.860. Glyceryl tristearate, a component of glyceryl palmitostearate, is approved as a multipurpose food additive in 21 CFR 172.811. Glyceryl monostearate is affirmed as GRAS (21 CFR 184.1324).

The Select Committee on GRAS Substances (SCOGS) reviewed all available toxicological studies on mono- and diglycerides and concluded:

There is no evidence in the available information on mono- and diglycerides of fat-forming fatty acids that demonstrates or

suggests reasonable grounds to suspect a hazard to the public when they are used at levels that are now current or that might reasonably be expected in the future. (Ref. 4, p. 23.)

The Joint Expert Committee on Food Additives (JECFA) of the Food and Agriculture Organization and the World Health Organization (FAO/WHO) has also reviewed the safety of mono- and diglycerides. Based on its review, JECFA has concluded that no limit on the acceptable daily intake of mono- and diglycerides need be established (Ref. 5).

III. Conclusion

FDA concludes that there is no meaningful difference between the components of glyceryl palmitostearate and dietary fats or the products of digestion of fats. The agency further concludes that there will not be a materially significant increase in exposure to these substances from the petitioned use of glyceryl palmitostearate. The safety of the mono- and diglyceride components of glyceryl palmitostearate has been reviewed by independent bodies of experts qualified by training and experience to evaluate the safety of food ingredients. These experts have concluded that mono- and diglycerides are safe. The information that the agency used to arrive at these conclusions is publicly available in published form (Refs. 1, 3, 4, and 5).

FDA, therefore, concludes that the petitioned use of glyceryl palmitostearate fully meets the requirements outlined in § 170.30(b) for GRAS affirmation based on scientific procedures. Therefore, in accordance with 21 CFR 184.1(b)(1), the agency is affirming that the use of glyceryl palmitostearate as a formulation aid in excipients for tablets is GRAS with no limitations other than current good manufacturing practice. The agency is listing the specific use as a formulation aid in excipients for tablets in the regulation solely to reflect that the affirmation of GRAS status is based on the evaluation of this use.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub.

L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact on small entities. Because no current activity is prohibited by this final rule, the compliance cost to firms is zero. Because no increase in the health risks faced by consumers will result from this final rule, total costs are also zero. Potential benefits include wider use of this substance because of reduced uncertainty concerning its GRAS status, and any resources saved by eliminating the need to prepare further petitions to affirm the GRAS status of this substance for this use. The agency certifies, therefore, that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. References

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

1. Gurr, M. I., and A. T. James, *Lipid Biochemistry: An Introduction*, John Wiley and Sons, Inc., New York, 1975.
2. Memorandum dated September 6, 1988, from M. Dinovi to J. Ziyad, "GRP 8G0344—Parxel Int. Corp. (PI) for Gattefossé, SA. Glycerol Palmitostearate."
3. Park, Y. K., and E. A. Yetley "Trend Changes in Use and Current Intakes of

Tropical Oils in The United States" *American Journal of Clinical Nutrition* 51:738-748, 1990.

4. Select Committee on GRAS Substances. "Evaluation of the Health Aspects of Glycerin and Glycerides as Food Ingredients" (SCOGS-30) PB-254 536, 1975.

5. Food and Agriculture Organization of the United Nations, "Toxicological Evaluation of Some Food Additives Including Anticaking Agents, Antimicrobials, Antioxidants, Emulsifiers and Thickening Agents." FAO Nutrition Meetings Report Series No. 53A, Rome, 1974.

List of Subjects in 21 CFR Part 184

Food additives, Food ingredients, 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, 21 CFR 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, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. New § 184.1329 is added to subpart B to read as follows:

§ 184.1329 Glycerol palmitostearate.

(a) Glycerol palmitostearate is a mixture of mono-, di-, and triglycerol esters of palmitic and stearic acids made from glycerin, palmitic acid, and stearic acid.

(b) The ingredient meets the following specifications:

(1) The substance is a mixture of mono-, di-, and triglycerides of palmitic acid and stearic acid.

(2) Heavy metals (as lead): Not more than 10 parts per million.

(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 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: November 16, 1995.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition. [FR Doc. 95-30125 Filed 12-11-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Parts 510, 520, and 522

Animal Drugs, Feeds, and Related Products; Diphenylhydantoin Sodium Capsules, et al.

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions of the regulations that reflect approval of one new animal drug application (NADA) held by Parke-Davis, Division of Warner-Lambert Co., three held by Akorn, Inc., and one held by Veterinary Research and Development, Inc. All of the sponsors submitted written requests that the agency withdraw approval of the NADA's. In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: December 22, 1995.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0159.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of the following NADA's:

NADA No.	Drug name	Sponsor name and address
6-032	Diphenylhydantoin sodium capsules	Parke-Davis, Division of Warner-Lambert Co., 201 Tabor Rd., Morris Plains, NJ 07950
12-444	Sterile prednisolone suspension	Akorn, Inc., 100 Akorn Dr., Abita Springs, LA 70420
94-978	Phenylbutazone injection	Do.
110-046	Dexamethasone injection	Do.
140-904	Copper disodium edetate injection	Veterinary Research and Development, Inc., P.O. Box 1299, Truckee, CA 95734