not appear to have a significant economic impact on a substantial number of small entities. 51 FR 40005, 40014 (1986). In its subsequent Notice, the Commission noted that the proposed amendments did not change the regulations sufficient to alter its previous "no impact" determination; nonetheless, to ensure that no substantial impact was being overlooked, the Commission requested public comment on the effect of the proposed regulations on costs, profitability, competitiveness, and employment in small entities. 54 FR 31541 (1989).

Two of the comments received during the comment period for promotional materials discussed the effect that regulations requiring rotation based upon date of dissemination would have on small businesses. The Smokeless Tobacco Council noted that smaller smokeless tobacco manufacturers may be unable to absorb any additional production costs, and may eliminate their promotional programs. The Smokeless Tobacco Council and Conwood Tobacco Company noted that small suppliers may be unable to make the necessary adjustments. No other comments on burden were received during the 1993 comment period for promotional materials and no comments on burden were received during the 1995 comment period for utilitarian items. By permitting rotation based upon date of order or date of dissemination, the final regulations will avoid any of these potential burdens on small entities. Thus, the Commission certifies that the amendments will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. § 605(b) (1982).

IV. Effective Date

During the comment period concerning the proposed regulations for promotional items, the Commission received two comments requesting that if the Commission adopts a requirement that promotional items rotate according to the date of dissemination, the Commission include a grandfather clause delaying the effective date of the rule for at least two years from publication of the final rule, to enable companies to use up their existing inventory of materials, and to allow suppliers time to make the necessary adjustments.13 The Commission, however, does not believe that any grandfather period is necessary given the flexibility permitted by the amended

regulations. In addition, the Commission notes that the major smokeless tobacco manufacturers have all previously filed plans calling for rotation based on date of order, one of the permitted methods of rotation under the amended regulations. However, the Commission will provide thirty (30) days for companies to come into compliance with these amendments. Thus, the effective date for the regulations governing the date that serves as the basis for rotating warnings on promotional materials is thirty (30) days from the date of publication of the final rule.

List of Subjects in 16 CFR Part 307

Health warnings, Smokeless tobacco, Trade practices.

Accordingly, Part 307 of 16 CFR Chapter I is amended as follows:

PART 307—REGULATIONS UNDER THE COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT OF 1986

1. The authority for Part 307 continues to read as follows:

Authority: 15 U.S.C. 4401 et seq.

2. Section 307.12(b) is revised to read as follows:

§ 307.12 Rotation, display, and dissemination of warning statements in smokeless tobacco advertising.

* * * * *

(b) Each manufacturer, packager, or importer of a smokeless tobacco product must submit a plan to the Commission or its designated representative that ensures that the three warning statements are rotated every four (4) months in alternating sequence. There may be more than one system, however, that complies with the Act and these regulations. For example, a plan may require all brands to display the same warning during each four-month period or require each brand to display a different warning during a given fourmonth period. A plan shall describe the method of rotation and shall include a list of the designated warnings for each four-month period during the first year for each brand. A plan shall describe the method that will be used to ensure the proper rotation in different advertising media in sufficient detail to ensure compliance with the Act and these regulations, although a number of different methods may satisfy these requirements. For example, a satisfactory plan for advertising in newspapers, magazines, or other periodicals could provide for rotation according to either the cover or closing date of the publication. A satisfactory

plan for posters and placards, other than billboard advertising, could provide for rotation according to either the scheduled or the actual appearance of the advertising. A satisfactory plan for point-of-sale and non-point-of-sale promotional materials such as leaflets, pamphlets, coupons, direct mail circulars, paperback book inserts, or non-print items, or for utilitarian objects, could provide for rotation according to the date the materials or objects are ordered by the smokeless tobacco manufacturer, or the date the objects or materials are scheduled to be disseminated, provided that the production of such materials or objects is carried out in a manner consistent with customary business practices.

By direction of the Commission. Donald S. Clark,

Secretary.

[FR Doc. 96–22221 Filed 8–29–96; 8:45 am] BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 85G-0335]

Direct Food Substances Affirmed as Generally Recognized as Safe; Enzyme-Modified Lecithin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that the use of enzyme-modified lecithin as a direct human food ingredient is generally recognized as safe (GRAS). This action is in response to a petition filed by Kyowa Hakko Kogyo Co., Ltd.

DATES: Effective August 30, 1996. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of two publications listed in new § 184.1063, effective August 30, 1996.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076. SUPPLEMENTARY INFORMATION:

I. Background

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

¹³ Comments of Smokeless Tobacco Council at 7 (March 18, 1993); United States Tobacco Co. at 23 (March 18, 1993).

Kyowa Hakko Kogyo Co., Ltd., Tokyo, Japan, submitted a petition (GRASP 5G0301) proposing that enzymemodified lecithin be affirmed as GRAS as a direct human food ingredient.

FDA published a notice of filing of this petition in the Federal Register of August 27, 1985 (50 FR 34758), and gave interested parties an opportunity to submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. FDA received two comments in response to that notice. One of the comments stated that the specifications proposed by the petitioner for enzymemodified lecithin did not agree with the specifications for lecithin in the Food Chemicals Codex, 3d ed. (1981) and argued that because of the differences in the specifications, enzyme-modified lecithin should be the subject of a food additive petition rather than a GRAS affirmation petition. FDA finds that the specifications of enzyme-modified lecithin need not agree with those of lecithin, because the two substances are chemically different. The agency further concludes that the differences between the specifications should not affect the classification of this petition. The second comment endorsed the petitioned use of enzyme-modified lecithin. Subsequently, the same commenter requested that FDA regulate enzyme-modified lecithin under the existing GRAS affirmation regulation for lecithin (§ 184.1400) (21 CFR 184.1400)). The agency concludes that because the chemical composition of enzyme-modified lecithin is different than that of lecithin, enzyme-modified lecithin should be regulated separately.

II. 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 substances added to food. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, experience based on common use in food (§ 170.30(a)). General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). In its petition, Kyowa Hakko Kogyo Co., Ltd., relies on scientific procedures, primarily published scientific papers and books,

corroborated by unpublished information, to demonstrate that enzyme-modified lecithin is GRAS.

III. Identity, Production, and Technical Effect

Lecithin is a complex mixture primarily composed of phospholipids, triglycerides, fatty acids, and carbohydrates (Refs. 1 and 2). The removal of most of the triglycerides and fatty acids of lecithin produces an "oilfree" or "deoiled" lecithin with a 90 percent or more phospholipid content. The enzyme phospholipase A_2 , identified with the Enzyme Commission (EC) number EC 3.1.1.4, converts the principal phospholipids of lecithin to their corresponding lysophospholipids. This reaction produces enzymemodified lecithin (Refs. 3 through 6).

Enzyme-modified lecithin is prepared from various types of crude or deoiled lecithin, using either purified phospholipase A_2 or pancreatin, an enzyme preparation from porcine pancreas that contains phospholipase A_2 . Added calcium chloride supplies calcium ions required for the activation of phospholipase A_2 . The process is carried out at pH 6 to 10 and within the temperature range of 30 to 70° C. At completion, phospholipase A_2 is inactivated by raising the temperature to 90 to 100° C.

The resulting enzyme-modified lecithin contains lysophospholipids and fatty acids produced by the enzymic reaction, as well as other components of lecithin (e.g., phospholipids, carbohydrates). Inactivated phospholipase A₂ and calcium chloride are also present in enzyme-modified lecithin. The exact composition of enzyme-modified lecithin varies depending on the type and the composition of lecithin used and on the degree of modification of lecithin achieved during the production of enzyme-modified lecithin (Ref. 7).

The petitioner intends to use enzyme-modified lecithin as an emulsifier in various foods, including bakery products, pasta products, margarine, mayonnaise, and salad dressings. The petition contains a published report and several patents demonstrating the effectiveness of enzyme-modified lecithin as an emulsifier in foods (Refs. 4, 5, 6, 8, and 9).

IV. Safety Evaluation

In evaluating the safety of enzymemodified lecithin, the agency considered the following issues: (1) The safety of lecithin and phospholipase A_2 , (2) the safety of enzyme-modified lecithin, (3) exposure to levels of the ingredient in food, and (4) specifications.

A. The Safety of Lecithin and Phospholipase A_2

FDA has affirmed lecithin as GRAS (§ 184.1400). Therefore, the agency has no safety concerns about the use of lecithin for the manufacture of enzymemodified lecithin.

Phospholipase A_2 is one of the digestive enzymes present in the pancreatic juice of mammals, including humans (Refs. 10 through 12) Phospholipase A₂ is irreversibly inactivated by heat at the end of the manufacture of enzyme-modified lecithin. Active and inactive enzymes are constituents of many foods normally consumed by humans. Therefore, FDA concludes that inactive phospholipase A₂ in enzyme-modified lecithin will be digested like any other protein present in food. The agency also notes that calcium chloride, which is used to activate phospholipase A₂ during the production of enzyme-modified lecithin, has been affirmed as GRAS (21 CFR 184.1193).

B. The Safety of Enzyme-Modified Lecithin

The end products of the modification of lecithin by phospholipase A_2 are lysophospholipids and fatty acids. Fatty acids are normal constituents of lecithin. They also occur naturally in many foods and form in the human body during normal cellular metabolism (Refs. 11 and 12). FDA has approved the use of salts of fatty acids as binders, emulsifiers and anticaking agents in food (21 CFR 172.863). Therefore, the agency has no safety concerns about the presence of fatty acids in enzymemodified lecithin.

Numerous published reports establish that the lysophospholipids produced during the manufacture of enzymemodified lecithin also occur naturally in a variety of foods, especially in cereal grains and eggs (Refs. 13 through 19). Furthermore, these lysophospholipids form in the human body from the action of pancreatic phospholipase A_2 on dietary lecithin (Refs. 11 and 12).

FDÅ reviewed several published studies suggesting that under certain pathologic conditions the intestinal fluid containing lysophospholipids may regurgitate into the stomach and damage the stomach mucosal tissue (Refs. 12 and 20 through 23). The agency evaluated these studies in light of the possible adverse effects of enzymemodified lecithin ingested in food. FDA concludes that the results of the studies suggesting that regurgitated lysophospholipids may damage the

stomach mucosal tissue are not relevant to the food ingredient uses of enzyme-modified lecithin, because the lysophospholipids present in enzyme-modified lecithin will be emulsified within a large excess of undigested food, which would provide a physical barrier to direct interaction of the lysophospholipids with the mucosal lining.

Moreover, in 1979, the Select Committee on GRAS Substances reviewed the available information on the metabolism of lecithin, including its breakdown to lysophospholipids in the human body, and concluded that there was no evidence of a hazard to the public from the use of lecithin in food at existing levels or levels that might reasonably be expected in the future (Ref. 24).

FDA also reviewed one published animal feeding study included in the petition (Ref. 6). During this study two groups of rats were fed for 3 and 13 weeks, respectively, diets containing various doses of enzyme-modified lecithin. The results of this study did not reveal any significant adverse effects in rats attributable to enzyme-modified lecithin.

Furthermore, the petitioner provided one unpublished corroborative feeding study. During this study enzymemodified lecithin was administered to rats at a dose of 2,000 milligrams per kilogram body weight per day (mg/kg bw/d) for 30 days, followed by 6 days per week for 60 days, for a total of 90 days. The results of this study did not reveal any adverse effects on the gastric mucosa of the rats or any other significant adverse effects attributable to enzyme-modified lecithin.

C. Estimated Exposure Levels

Based on the petitioner's intended use of enzyme-modified lecithin in a manner similar to lecithin, and using information on consumption of various food categories containing lecithin (Ref. 25), the agency calculated the estimated daily intake (EDI) of enzyme-modified lecithin as 326 mg/person/d.

Moreover, the data obtained in the published 13-week rat feeding study (Ref. 6) showed no adverse effects at a level of 20 grams enzyme-modified lecithin/kg bw/d. Application of a 1,000-fold safety factor to this value produces, for a 60 kg person, an acceptable daily intake of 1,200 mg enzyme-modified lecithin/person/d, which exceeds the EDI reported above (326 mg/person/d).

D. Specifications

FDA reviewed the specifications for enzyme-modified lecithin suggested in

the petition. The agency notes that the petitioner originally suggested a lead limit of not more than 10 parts per million. However, after discussions with FDA about the agency's desire to limit human exposure to lead to the lowest level possible in food (see 59 FR 5363, February 4, 1994), the petitioner amended the petition to suggest a lead limit of not more than 1.0 part per million. FDA agrees that this lower limit should be adopted. Also, the agency notes that in a notice published in the Federal Register of March 14, 1994 (59 FR 11789), the National Academy of Sciences/Institute of Medicine Committee on Food Chemicals Codex (the Committee) announced its new policy that inclusion of arsenic limits in Food Chemicals Codex monographs should no longer be routine, but should be considered on an "as-needed" basis. To implement this new policy, the Committee proposed to delete the arsenic specification for various Food Chemicals Codex substances, including lecithin. The proposal became final when the fourth edition of the Food Chemicals Codex was published in 1996. FDA agrees that a specification for arsenic in enzyme-modified lecithin is not necessary. Therefore, no such specification is being adopted in this final rule. FDA concludes that the other specifications suggested in the petition should be adopted.

V. Conclusion

FDA has evaluated the published information in the petition, along with other corroborative information, and finds that the use of enzyme-modified lecithin as an emulsifier in foods is GRAS.

Furthermore, these data show no potential risk from any foreseeable use of enzyme-modified lecithin. Therefore, in accordance with 21 CFR 184.1(b)(1), the agency is affirming that the use of enzyme-modified lecithin in foods is GRAS with no limits other than current good manufacturing practice.

VI. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental impact analysis report submitted under previous 21 CFR part 25, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Analysis of Impacts

FDA has examined the economic implications of this final rule affirming the GRAS status of the use of enzymemodified lecithin in foods under Executive Order 12866. 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 issues; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. 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.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the significant economic impact of the rule on small entities. This final rule recognizes the applicability of a statutory exemption. The impact of the rule is to remove uncertainty about the regulatory status of enzyme-modified lecithin for use in foods. Therefore pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commissioner certifies that this rule will not have a significant economic impact on a substantial number of small entities.

VIII. Effective Date

As this rule recognizes an exemption from the food additive definition in the Federal Food, Drug, and Cosmetic Act, and from the approval requirements applicable to food additives, no delay in effective date is required by the Administrative Procedure Act (5 U.S.C. 553(d)). The rule will therefore be effective immediately (5 U.S.C. 553(d)(1)).

IX. References

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

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3. Van Nieuwenhuyzen, W., "The Industrial Uses of Special Lecithins: A Review," *Journal of American Oil Chemists' Society*, 58:886–888, 1981.

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- Journal of Surgical Research, 42:290-297, 1987.
- 23. Ritchie, W. P., "Other Causes of GI Mucosal Injury: Upper Intestinal Content,' Clinical and Investigative Medicine, 10:264-269, 1987.
- 24. Select Committee on GRAS Substances, "Evaluation of the Health Aspects of Lecithin as a Food Ingredient," Report No. 106, Life Sciences Research Office, Federation of American Societies for Experimental Biology, Bethesda, Maryland, 1979.
- 25. Memorandum from the Food Additive Chemistry Evaluation Branch to the GRAS Review Branch, June 3, 1985.

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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 § 184.1063 is added to subpart B to read as follows:

§184.1063 Enzyme-modified lecithin.

- (a) Enzyme-modified lecithin is prepared by treating lecithin with either phospholipase A₂ (EC 3.1.1.4) or pancreatin.
- (b) The ingredient meets the specifications in paragraphs (b)(1) through (b)(8) of this section. Unless otherwise noted, compliance with the specifications listed below is determined according to the methods set forth for lecithin in the Food Chemicals Codex, 4th ed. (1996), pp. 220–221, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.
- (1) Acetone-insoluble matter (phosphatides), not less than 50.0 percent.
 - (2) Acid value, not more than 40.
- (3) Lead, not more than 1.0 part per million, as determined by atomic absorption spectroscopy.

- (4) Heavy metals (as Pb), not more than 20 parts per million.
- (5) Hexane-insoluble matter, not more than 0.3 percent.
 - (6) Peroxide value, not more than 20.
 - (7) Water, not more than 4.0 percent.
- (8) Lysolecithin, 50 to 80 mole percent of total phosphatides as determined by "Determination of Lysolecithin Content of Enzyme-Modified Lecithin: Method I," dated 1985, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.
- (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 as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:
- (1) The ingredient is used as an emulsifier as defined in § 170.3(o)(8) of this chapter.
- (2) The ingredient is used at levels not to exceed current good manufacturing practice.

Dated: July 31, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–22246 Filed 8–29–96; 8:45 am] BILLING CODE 4160-01-F

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 623

[AR 700-131]

Loan of Army Materiel and Property Returns; Correction

AGENCY: Department of the Army, DoD. **ACTION:** Correcting amendments.

SUMMARY: This document contains corrections to the final regulations which were published on September 18, 1980 (45 FR 62038) the regulations related to the process of Army property returns.