DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

DOCKETS TRANSMITTAL MEMO

0424 '03 JAN 27 P2:19

Date: JAN 23 2003

From: Consumer Safety Officer, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-821

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Egg Lecithin

Firm: Belovo Inc.

Date Received by FDA: 7/15/02

90-Day Date: 10/13/02

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Gloria Chang

Gloria Chang, R.Ph./Interdisciplinary Scientist

Attachments

95S-0316

RPT142

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 17 2002

Michael R. Hawes, President
Belovo Inc.
Post Office Box 4092
Pinehurst, North Carolina 28374

Dear Mr. Hawes:

This is to inform you that the notification, dated July 9, 2002 you submitted pursuant to 21 U.S.C. 350b(a)(2) was received and filed by the Food and Drug Administration (FDA) on July 15, 2002. Your notification concerns the substance, Egg Lecithin, that you assert is a new dietary ingredient. You describe your product as a dietary supplement that contains the following:

A. Powder form: 1.7 grams of egg lecithin (40 mg docohexaenoic acid (DHA) and 80 mg arachidonic acid (ARA) Fatty Acids)) per 3.4 g pouches. You state that the other ingredient is 170 mg choline per 3.4 g pouch. You indicate that the conditions of use recommended in the labeling are:

Age Years	Body Wt. (lbs)	Recommended X pouches/day
1-3	22-33	1
3 and Up	> 33	2

B. Liquid form: 360 mg egg lecithin (26.5 mg DHA and 29.25 mg ARA) per 10 mL container pouch with conditions of use recommended in the labeling as:

Age Year	Body Wt. (lbs)	Recommended X Pouches/day
1-2	22-27	3
2-3	27-33	4
3 and up	>33	5

C. Other form (not specifically described): 0.75 g egg lecithin (15 mg DHA and 30 mg ARA) per pouch. Other ingredient is 65 mg choline per pouch. Recommended conditions of use in labeling are:

One pouch daily for children 1 – 12 years of age
One pouch twice daily during pregnancy and lactation

In accordance with 21 C.F.R 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. Please note that the acceptance of this notification for filing is only a procedural matter in accordance with 21 CFR 190.6(c) acknowledging FDA's receipt of your notification. Further, if we find that the information submitted is incomplete or additional substantive information is needed or submitted, the effective filing date may be reset (i.e., assigned a new filing date) subject to the date that we receive the complete information either as an amendment to the notification or as a new complete notification. FDA will notify the manufacturer of the new filing date.

You should also be aware that for 75 days after the effective filing date, you must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains egg lecithin.

Please note that FDA's failure to respond to a notification within or after the 75-day period does not constitute a finding by the agency that the new dietary ingredient or the dietary supplement that contains the new dietary ingredient is safe or is not adulterated under section 402 of the act. (21 CFR 190.6(5)(f)). Further, FDA is not precluded from taking action in the future against a dietary supplement containing egg lecithin containing the amounts of DHA and ARA indicated above if it is found to be unsafe, adulterated or misbranded. It is the responsibility of the manufacturer or distributor of a dietary supplement to ensure that it is safe, properly labeled and complies with all applicable requirements of the Federal Food, Drug and Cosmetic Act and implementing regulations in Title 21 of the Code of Federal Regulations as well as any other applicable Federal laws and regulations.
Importantly, any new dietary ingredient for use in a dietary supplement that FDA has reviewed through the premarket notification process is not "approved" or "authorized" by the agency.

Your notification will be kept confidential for 90 days from the date of the effective filing date. Therefore, after October 13, 2002, your notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notification will not be disclosed to the public.

For your information, the following FDA Internet sites and their corresponding links may be useful:

http//www.cfsan.fda.gov~dms/supplmnt.html
http//www.cfsan.fda.gov~lrd/fr97923e.html (21 CFR 190.6)
http//www.cfsan.fda.gov~dms/ds-info.html
http//www.cfsan.fda.gov~dms/ds-ind.html
http//www.cfsan.fda.gov~dms/ds-labl.html
http//www.cfsan.fda.gov~lrd/fr97923b.html
http//www.cfsan.fda.gov~dms/ds-labl.html#structure
http//www.cfsan.fda.gov~/bcp/conline/pubs/buspubs/dietsupp.htm

Please contact me at (301) 436-2371, if you have any questions concerning this matter.

Sincerely yours,

Gloria Chang

Gloria Chang, R.Ph
Interdisciplinary Scientist
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Belovo
ECO SCIENCE & TECHNOLOGY

July 9, 2002

Christine Lewis Taylor, Ph. D., Director
Office of Nutrition Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5700 Paint Branch Parkway
College Park, MD 20740

Dear Dr. Taylor:

The enclosed document is the 75-day premarket notification for the new dietary ingredient egg lecithin, submitted pursuant to 21 CFR 190.6. The egg lecithin contributes arachidonic acid and docohexaenoic acid in supplements. Belovo Incorporated is the distributor for the ingredient that will be used in dietary supplements and also plans to market two of the three dietary supplements described in the notification.

If you have any questions or if I can be of any assistance, I can be reached at 910-295-2320.

Sincerely,

Michael R. Hawes

Michael R. Hawes
President
Belovo Incorporated

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Belovo
SCIENCE & TECHNOLOGY

PREMARKET NOTIFICATION FOR NEW DIETARY INGREDIENT PURSUANT TO 21 CFR 190.6

1. Name and address of distributor of new dietary ingredient:
Belovo Incorporated
P. O. Box 4092
Pinehurst, NC 28374

2. Name of the new dietary ingredient that is the subject of the pre-market notification:
Egg Lecithin

3. Description of the dietary supplements that contain the new dietary ingredient:
(a) DHA and ARA Fatty Acids Supplement, powder form
(i) Level of the new dietary ingredient in the supplement:

1.7g egg lecithin (40 mg DHA and 80 mg ARA) per 3.4 gram pouch

[other dietary ingredient:170mg choline per 3.4g pouch]
(ii) Conditions of use recommended in the labeling of the dietary supplement:

Age Years	Body Wt. lbs	Recommended X pouches/day
1 –3	22 –33	1
3 and Up	> 33	2

Mix or sprinkle one pouch into cereal, non-dairy beverages, juice, milk or water. X times per day.

(b) DHA and ARA Fatty Acids Supplement, liquid form
(i)Level of the dietary ingredient in the supplement:

360 mg egg lecithin per 10 ml container

Sources of DHA and ARA

	DHA	ARA
Egg Lecithin	8.24	17.89
Tuna Fish Oil	18.26	1.42
Mortierella Alpine *		9.94
Totals	26.5	29.25

* The oil is derived from *Mortierella Alpina* , (for examples, Martek ARASCO, DSM OPTIMAR and others.)

[other dietary ingredient: 35 mg choline per 10 ml]

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(ii) Conditions of use recommended in the labeling of the dietary supplement:

Age Years	Body Wt lbs	Recommended X pouches/day
1 – 2	22 –27	3
2 – 3	27 –33	4
3 and Up	>33	5

Open one portion, mix contents with liquids like milk or water. Consume immediately after opening. X times per day.

(c) DHA and ARA Fatty Acids Supplement

(i)Level of the new dietary ingredient in the supplement:

0.75 g egg lecithin (15mg DHA, 30 mg ARA) per pouch

[other dietary ingredient: 65 mg choline per pouch)

(ii)Conditions of use recommended in the labeling of the dietary supplement:

one pouch daily for children 1 – 12 years of age
one pouch twice daily during pregnancy and lactation

Mix or sprinkle into cereal, non-dairy beverages, juice, milk or water.

4. History of use and evidence of safety for the new dietary ingredient, egg lecithin, when used under the conditions recommended:

The egg lecithin product subject to this Notice is a purified phospholipid fraction of yolk from chicken eggs using a process approved by the EU under its Novel Foods regulations (Novel Food, EC 258/97; Attachment 1). The egg lecithin product consists of at least 95% lipids of which 85% ± 2.5 % is phospholipids, 7%± 0.5% free fatty acids and 7% ± 0.5 % cholesterol. The phospholipids of the egg yolk product are essentially the same as the lecithins derived from plant food oils which have been affirmed as generally recognized as safe (GRAS) by FDA under 21 CFR 184.1400 as follows:

§ 184.1400 Lecithin.
(a) Commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of other lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn oils. Lecithin is bleached, if desired, by hydrogen peroxide and benzoyl peroxide and dried by heating.

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(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 166-167, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.
(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.
(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.
[48 FR 51150, Nov. 7, 1983]

The Food Chemicals Codex specifications as cited in the regulation are as follows:

Acetone-insoluble matter (phosphatides)..... not less than 50%
Acid value .....not greater than 36
Arsenic(as As).....not greater than 3 ppm
Heavy Metals (as Pb).....not more than 0.004%
Lead.....not more than 10 ppm
Hexane insoluble matter.....not more than 0.3%
Peroxide value.....not more than 100
Water.....not more than 1.5%

The egg lecithin product will meet or exceed the above Food Chemicals Codex specifications required by FDA's GRAS affirmation regulation for lecithin. Such specifications are considered appropriate for assuring safety of the egg lecithin product in consideration of its source, food grade eggs, and its manufacturing process, Cosolute Induced Phase Separation (CIPS)[Novel Food EC 258/97], which is only a physical process and does not result in chemical changes in the finished phospholipid product. The composition of the egg lecithin product is given in Table 1 below.

Table 1
Phospholipid composition of the egg lecithin product

Individual phospholipids	Per cent of total phospholipids
Phosphatidylcholine	70-75
Phosphatidylethanolamine	15-20
Lysophosphatidylcholine	3-4
Sphingomyelin	2-3
Lysophosphatidylethanolamine	1-2
Phosphatidylinositol	2-3

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As seen from inspection of Table 1, the three principal phospholipids in GRAS affirmed lecithin represent 87-98 % of the phospholipids in the egg lecithin product. Thus, not only will the chemical specifications for egg lecithin be the same as for GRAS affirmed lecithin, the phospholipid composition of the two lecithins is nearly the same.

However, two significant differences exit between the two lecithins. The first, which relates to the reason for its use, is the fatty acids in the egg lecithin product contain relatively high amounts of long chain polyunsaturated fatty acids (LC-PUFA), particularly arachidonic acid (ARA) and docosahexaenoic acid (DHA) which are essentially absent in vegetable oils. The fatty acid profile from the phospholipids of egg product lecithin is given below:

Table 2
Fatty acid Spectrum

Name	Formula	Percent of total fatty acids
Palmitic acid	C16:0	25.6
Palmitoleic acid	C16:1(w7)	0.96
Stearic acid	C18:0	15.2
Oleic acid	C18:1 (w9)	27.36
Linoleic acid	C18:2 (w6)	16.58
Linolenic acid	C18:3(w3)	0.19
Arachidonic acid	C20:4(w6)	6.04
Eicosapentaenoic acid	C20:5(w3)	n.d.
Docosapentaenoic acid	C22:5(3)	0.23
Docosahexaenoic acid	C22:6(w3)	3.10

The level of ARA and DHA in egg lecithin based on total fatty acids is 6.0 and 3.1 % by weight, respectively. Given fatty acids represent approximately 60% of the total phospholipid molecule, ARA and DHA are 3.6% and 1.8% by weight of total phospholipid, respectively. As indicated above, the recommended individual dose is 80 mg ARA and 40 mg DHA, which, based on the above percentages, will require about 2 grams of egg lecithin phospholipids. This quantity of egg lecithin product contains about 135 mg cholesterol or 45% of the daily value based on a 2000 calorie diet. The presence of cholesterol is the second difference between egg lecithin and lecithin from vegetable oils which contain only typical plant sterols rather than cholesterol.

Based on data in the Lipid Handbook, second edition (attachment 2) an egg contains about 2 grams of phospholipids and 290 mg cholesterol, or about twice as much cholesterol as present in 2 grams of the egg lecithin product. According to the food intake survey conducted by the USDA, Continuing Survey of Food Intake by Individuals, 1989 to 1991,

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the daily consumption of eggs in any form by the 90th percentile consumer is 87 grams or the equivalent of about 1.3 eggs per day or 300 to 400 mg cholesterol. The recommended daily dose of the egg lecithin product will take care not to exceed the daily value for cholesterol. Thus, under recommended conditions of use, the presence of cholesterol should not raise questions about the safety of the egg lecithin product. The recommended levels of ARA and DHA of 80 and 40 mg/individual dose does not raise any questions of safety for use as a supplement given that ARA and DHA have been marketed for some time as dietary supplements and ARA and DHA have been GRAS noticed (GRN 000041, May 17, 2001) for use in infant formula at a level of 30mg/kg bw/day for both ARA and DHA. As this dose equates to 300 mg per 10 kg child (typically, 1 year olds are 10 kg or heavier), the recommended dose of 80 mg ARA and 40 mg DHA for one year olds would be well within the safe range.

It is concluded that the recommended conditions of use of the subject egg lecithin product (New Dietary Ingredient) is reasonably expected to be safe as required (21 CFR 190.6) based on the source being a common food and being of food grade, on meeting the FCC compositional and safety related specifications of GRAS affirmed lecithin, and on the recommended levels of use not causing excessive intake of nutrients. The process used to produce the egg lecithin product is entirely physical and does not change the chemical composition of the phospholipids comprising the product. The process employs standard food processing techniques of Pasteurization and filtration combined with electrophoresis and resin separation using a resin consisting of carrageenan and alginic acid, both of which are approved for direct addition to food. The alginic acid is esterified with isopropanol, which is an approved solvent under 21 CFR 173.240, mixed with carrageenan, melted at 60 degrees C in brine to form potassium and calcium salts, and extruded to form the resin material. As no chemical changes occur in the phospholipids as the result of their isolation from egg yolk lipids by the above described processing, it is concluded that FCC specifications for lecithin are adequate to assure the egg lecithin product is reasonably expected to be safe under the conditions of recommended use as a dietary supplement.

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