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ORIGINAL SUBMISSION

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ANTHONY YOUNG
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July 9, 2002

By E-Mail and UPS Next Day

Alan M. Rulis, Ph.D.
Director, Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration (HFS-200)
1100 Vermont Avenue NW
Washington, D.C. 20201

Linda S. Kahl, Ph.D.

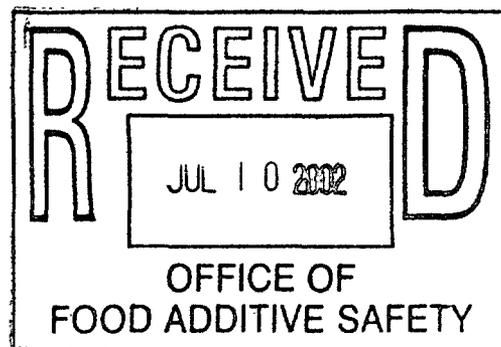
Michael T. Watson, Ph.D.

Division of Biotech and GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway, HFS-255
College Park, MD 20740

RE: GRAS Notification - HiDHA® Tuna Oil - (Please refer also to GRAS
Notice No. GRN 000097, Withdrawn on June 24, 2002 by Clover
Corporation, Ltd.)

Dear Drs. Rulis, Kahl and Watson:

Please substitute the enclosed CORRECTED VERSION of the GRAS Notification for HiDHA® Tuna Oil that was sent to you yesterday. This version corrects a substantive error in penultimate line of the second line of the second paragraph on page three.



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Please call me if you have any questions.

Sincerely,

Anthony L. Young

ALY/jjb
Enclosures

cc: Hamish Drummond
Managing Director
Clover Corporation Limited

James Heimbach, Ph.D.

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ANTHONY YOUNG
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July 8, 2002

CORRECTED VERSION

By E-Mail and UPS Next Day

Alan M. Rulis, Ph.D.
Director, Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration (HFS-200)
1100 Vermont Avenue NW
Washington, D.C. 20201

Linda S. Kahl, Ph.D.

Michael T. Watson, Ph.D.

Division of Biotech and GRAS Notice Review
Office of Food Additive Safety
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5100 Paint Branch Parkway, HFS-255
College Park, MD 20740

RE: GRAS Notification - HiDHA® Tuna Oil - (Please refer also to GRAS
Notice No. GRN 000097, Withdrawn on June 24, 2002 by Clover
Corporation, Ltd.)

Dear Drs. Rulis, Kahl and Watson:

We are counsel to Clover Corporation Limited, North Sydney, Australia (Clover), the sponsor of the withdrawn GRAS Notification for tuna oil that is referenced above. The notice informed the Food and Drug Administration of Clover's view that tuna oil is GRAS, through scientific procedures, for use in food as described in 21 CFR 184.1472(a)(3) with respect to certain food categories and levels of use in those food categories.

By letter on June 24, 2002 Clover requested the agency cease to evaluate the Clover GRAS Notice while Clover prepared a revised notice to change the maximum

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amounts of to be used in the foods listed in 21 CFR 184.1472(a)(3) to the below listed percent levels.

Please consider this the new and amended notification of the GRAS status of HiDHA® tuna oil to be used at the maximum levels listed below:

	<u>%</u>
Cookies, crackers	3.1
Breads, rolls	0.6
Fruit pies, custard pies	4.3
Cakes	6.2
Cereals	2.5
Fats, oils (but not infant formula)	12.3
Yogurt	2.5
Cheese products	3.1
Frozen dairy products	3.1
Meat products	6.2
Egg products	3.1
Fish products	12.3
Condiments	3.1
Soup mixes	1.8
Snack foods	3.1
Nut products	3.1
Gravies, sauces	3.1

It is the position of Clover that HiDHA® tuna oil is generally recognized as safe for use in foods at these levels. These use levels are set to provide the same content of EPA+DHA as is provided by menhaden oil as permitted by the 184.1472(a)(3). Clover has calculated the appropriate use levels using 20% as the amount of the EPA+DHA content of menhaden oil and 32.5% as the amount of the EPA+DHA content of HiDHA tuna oil. Clover calculates an estimated daily intake of EPA+DHA from the proposed uses of HiDHA tuna oil as a food ingredient of approximately 2.76 g/person per day. Since HiDHA tuna oil is offered merely as an alternative to menhaden oil, this represents no increase in the potential level of consumer exposure to these fatty acids.

Please substitute the attached **Table 2: Specifications for HiDHA® tuna oil products**, for the Table 2 that presently appears in GRAS Notice No. GRN 000097. Please substitute the attached **Table 3: Ingredient Listing for HiDHA® tuna oil products** for the Table 3 that presently appears in GRAS Notice No. GRN 000097. These tables take into account the High Oil Loading Powders that Clover intends to market.

The basis for this GRAS determination is through scientific procedures.

The data and information that are the basis for Clover's GRAS notification are appended to Clover's original notification, GRN No. 000097 which is incorporated by reference herein and modified by the enclosed Tables 2 and 3 and the use levels set forth above. Please note that while the Expert Panel Report submitted by Clover in support of this Notification and GRN No. 000097 concluded that tuna oil is GRAS for human use at approximately 4 grams per day, Clover is submitting this Notification at levels intended to provide for human use at no more than 3 grams per day and does not intend to market the product for other food ingredient uses.

On February 26, 2002, FDA issued a Proposed Rule ("Substances Affirmed as Generally Recognized as Safe: Menhaden Oil"; 67 FR 8744) that proposes. To reallocate the permitted food uses of menhaden oil while maintaining the estimated daily intake at less than 3.0 g. Should this rule become final, it is the intent of Clover to amend the uses of tuna oil to conform with the food categories specified in Table 2 of the Proposed Rule, at use levels that continue to provide the same maximum content of EPA+DHA as provided by menhaden oil for those uses.

Please direct any communications to me at the e-mail address above and to hamishd@clovercorp.com.au.

Please also be advised that Clover has retained James Heimbach, Ph.D. (202-237-6317), now an independent consultant, to assist Clover and its counsel with this Notification.

Thank you in advance for your prompt consideration of this Notification.

Sincerely,

Anthony L. Young

ALY/jjb
Enclosures
cc: Hamish Drummond
Managing Director
Clover Corporation Limited

James Heimbach, Ph.D.

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Table 2: Specifications for HiDHA[®] tuna oil products

Specification	HiDHA [®] Tuna Oil	HiDHA [®] Tuna Oil Powders	High Oil Loading Powders
Appearance	Pale yellow oil	White to light beige powder	Light beige powder
Odour	Faint fresh fish	bland	bland
%Total Fat	100%	24-30%	45-54%
Fatty Acid Profile*:			
Docosahexaenoic Acid (DHA), %*	25-28%	18-25%	23-28%
Eicosapentaenoic Acid (EPA), %*	5-8%	4-8%	4-8%
DHA+EPA,%	30 - 35%	24 - 30%	28 - 35%
Total omega-3 fatty acid content, %*	32-40%	26-34%	32-40%
Acid Value, mgKOH/g	max. 1.0	**	**
Peroxide Value, meq O ₂ /kg	max. 5	**	**
p-Anisidine Value	max. 20	**	**
Colour, Gardner	max. 4	**	**
Unsaponifiable Matter, %	max. 2	**	**
Lead, ppm	max. 0.1	**	**
Mercury, ppm	max. 0.1	**	**
Cadmium, ppm	max. 0.1	**	**
Arsenic, ppm	max. 0.1	**	**
Total Heavy Metals, ppm	max. 2	**	**
DDT, ppm	max. 0.05	**	**
DDE, ppm	max. 0.05	**	**
HCB, ppm	max. 0.05	**	**
PCB, ppm	max. 0.1	**	**
Lindane, ppm	max. 0.05	**	**
Yeast and Mould (cfu/g)	<100		
Standard Aerobic Plate Count (cfu/g)	<100	<1000	<1000
Enterobacteriaceae (cfu/g)	<100		
E. coli	ND in 1g		
Salmonella spp.	ND in 10g	ND in 25g	ND in 25g
Coliforms (37°C)		ND in 0.1g	ND in 0.1g
Coagulase positive staph.		ND in 0.01g	ND in 0.01g
Baccillus cereus		ND in 0.01g	ND in 0.01g

* Fatty acid composition is expressed as a percentage of fatty acid methyl esters prepared for GC analysis [% area method]

** The fat component of these products (HiDHA[®] Tuna Oil Powders and High Oil Loading Powders) have the same values as those listed in column 2 of the Table.

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Table 3: Ingredient Listing for HiDHA® tuna oil products

HiDHA® Tuna oil products	Ingredients	FDA Regulatory Status
HiDHA® Tuna oil	HiDHA® Tuna oil Mixed natural tocopherols	21 C.F.R. § 182.3890
HiDHA® Tuna oil Powders	HiDHA® Tuna oil Mixed natural tocopherols Hydrogenated palm oil Mono- and diglycerides of edible fatty acids Ascorbyl palmitate Modified food starch Citric acid Maltodextrin Sodium caseinate Whey Protein Concentrate Sodium ascorbate Lecithin dl-alpha tocopherol Propyl gallate Butylhydroxyanisole (BHA)	21 C.F.R. § 182.3890 GRAS 21 C.F.R. § 184.1505 21 C.F.R. § 182.3149 21 C.F.R. § 172.892 21 C.F.R. § 184.1033 21 C.F.R. § 184.1444 21 C.F.R. § 182.1748 21 C.F.R. § 184.1979c 21 C.F.R. § 182.3731 21 C.F.R. § 184.1400 21 C.F.R. § 182.3890 21 C.F.R. § 184.1660 21 C.F.R. § 182.3169
High Oil Loading Powders	HiDHA® Tuna oil Mixed natural tocopherols Sodium caseinate Whey protein isolate Glucose Sodium ascorbate Lecithin dl-alpha tocopherol Ascorbyl palmitate	21 C.F.R. § 182.3890 21 C.F.R. § 182.1748 GRN 000037 21 C.F.R. § 168.121 21 C.F.R. § 182.3731 21 C.F.R. § 184.1400 21 C.F.R. § 182.3890 21 C.F.R. § 182.3149

SUBMISSION END

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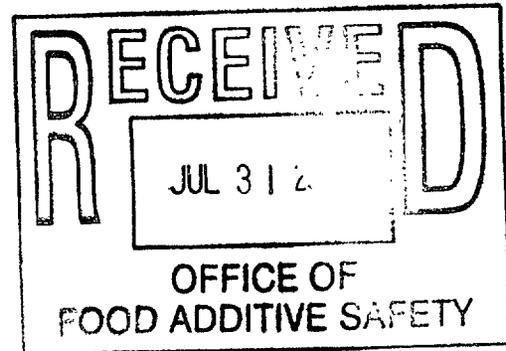


ANTHONY YOUNG
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July 30, 2002

By E-Mail and UPS Next Day

Karin E. Ricker, Ph.D.
Division of Biotech and GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway, HFS-255
College Park, MD 20740



RE: GRAS Notification No. 109 - HiDHA® Tuna Oil - (Please refer also to GRAS Notice No. GRN 000097, Withdrawn on June 24, 2002 by Clover Corporation, Ltd.)

Dear Dr. Ricker:

We are counsel to Clover Corporation Limited, North Sydney, Australia (Clover), the sponsor of the GRAS Notification for HiDHA® Tuna Oil tuna oil that is referenced above. This responds to your telephone request of July 26, 2002 that Clover clarify its GRAS Notification No. 109 with respect to the proposed changes in the GRAS regulation for menhaden oil and with respect to the proposed use of HiDHA® Tuna Oil in foods that use other added sources of EPA or DHA.

On February 26, 2002, the Food and Drug Administration published a proposed rule to amend its regulation on menhaden oil to reallocate the uses of menhaden oil (67 Fed. Reg. 8744). The food categories and maximum use levels of menhaden oil under the proposed rule are shown in the table below. The estimated daily intake of EPA+DHA under the reallocation remains at less than 3.0 g per person per day, the same as in the present regulation.

If the proposed rule is adopted, it is intention of the present GRAS Notification No. 109 that the uses of HiDHA® Tuna Oil would remain consistent with the permitted uses of menhaden oil, as shown in table set forth below. In making this calculation, HiDHA® Tuna Oil was substituted for menhaden oil so that the estimated daily intake of EPA+DHA and the cumulative effect of these fatty acids in the diet would be the same

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as for menhaden oil. Because HiDHA® Tuna Oil has a concentration of about 32.5 percent EPA+DHA, as compared with about 20 percent EPA+DHA in menhaden oil, the maximum proposed use levels for HiDHA® Tuna Oil are about 61 percent of those for menhaden oil. Thus, the concentration levels of EPA+DHA added to food would be the same for HiDHA® Tuna Oil as for menhaden oil and the estimated daily intake of EPA+DHA would remain at less than 3.0 g per person per day.

It should be noted that the maximum proposed uses for HiDHA® Tuna Oil in the table assume no other ingredient containing EPA and/or DHA is added to the food. You have asked that Clover consider limiting its proposed use of HiDHA® Tuna Oil to foods to which no other ingredient containing EPA and/or DHA has been added. Clover is willing to do so and FDA may consider GRAS Notification No. 109 to be amended to contain that restriction. However, Clover would prefer that if another such ingredient or ingredients is used in addition to HiDHA® Tuna Oil, that the total added EPA+DHA would not exceed the amount that would be provided by the proposed maximum use levels of HiDHA® Tuna Oil or menhaden oil when used alone. Clover asks that FDA consider this alternative and, if it is acceptable, that FDA consider GRAS Notification No. 109 to be amended in this fashion.

Maximum Levels of Use of Menhaden Oil and HiDHA® Tuna Oil
 Under the Proposed Rule for Menhaden Oil
 (67 Fed. Reg. 8744)

Category of Food*	Maximum Level of Use	
	Menhaden Oil	HiDHA® Tuna Oil
Baked goods and baking mixes (1)	5.0 percent	3.1 percent
Cereals (4)	4.0 percent	2.5 percent
Cheese products (5)	5.0 percent	3.1 percent
Condiments (8)	5.0 percent	3.1 percent
Egg products (11)	5.0 percent	3.1 percent
Fats and oils (12), but not in infant formula	12.0 percent	7.4 percent
Fish products (13)	5.0 percent	3.1 percent
Frozen dairy desserts (20)	5.0 percent	3.1 percent
Gravies and sauces (24)	5.0 percent	3.1 percent
Meat products (29)	5.0 percent	3.1 percent
Milk products (31)	5.0 percent	3.1 percent
Nut products (32)	5.0 percent	3.1 percent
Snack foods (37)	5.0 percent	3.1 percent
Soup mixes (40)	3.0 percent	1.8 percent
Nonalcoholic beverages (3)	0.5 percent	0.3 percent
Chewing gum(6)	3.0 percent	1.8 percent

Confections and frostings (9)	5.0 percent	3.1 percent
Dairy product analogs (10)	5.0 percent	3.1 percent
Gelatins and puddings (22)	1.0 percent	0.6 percent
Pastas (23)	2.0 percent	1.2 percent
Hard candy (25)	10.0 percent	6.2 percent
Jams and jellies (28)	7.0 percent	4.3 percent
Plant protein products (33)	5.0 percent	3.1 percent
Poultry products (34)	3.0 percent	1.8 percent
Processed fruit juices (35)	1.0 percent	0.6 percent
Processed vegetable juices (36)	1.0 percent	0.6 percent
Soft candy (38)	4.0 percent	2.5 percent
White granulated sugar (41)	4.0 percent	2.5 percent
Sugar substitutes (42)	10.0 percent	6.2 percent
Sweet sauces, toppings, and syrups (43)	5.0 percent	3.1 percent
*The number in parenthesis following each food category is the paragraph listing of that food category in 21 CFR 170.3(n).		

Please call me or Dr. Heimbach (202-237-8406) if you have any questions.

Sincerely yours,

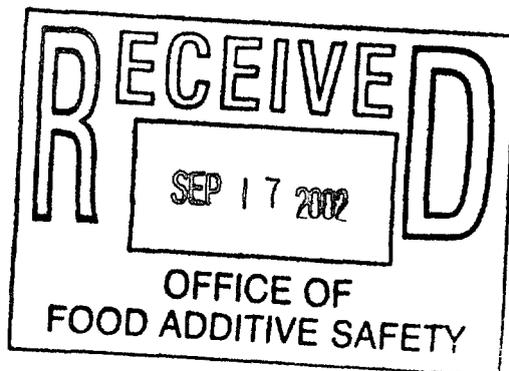
Anthony L. Young

ALY/jjb
Enclosures
cc: Hamish Drummond
Managing Director
Clover Corporation Limited

James Heimbach, Ph.D.

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September 13, 2002

BY E-MAIL AND UPS NEXT DAY

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Division of Biotech and GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway, HFS-255
College Park, MD 20740

RE: GRAS Notification No. 109 - HiDHA® Tuna Oil - (Please refer also to GRAS Notice No. GRN 000097, Withdrawn on June 24, 2002 by Clover Corporation, Ltd.)

Dear Dr. Ricker:

Thank you for telephone inquiry on Friday, August 30, seeking clarification of two points regarding the GRAS notification for Tuna Oil manufactured by Clover Corporation Ltd. (GRN #109, filed July 11, 2002). As counsel for Clover Corporation, the sponsor of the GRAS notification, we have contacted the company and are responding on their behalf. We apologize for the tardy response, but communications were slow.

GRN #109 notified FDA that Clover Corporation has determined that their Tuna Oil product known as HiDHA® Tuna Oil is GRAS for use in various foods as set forth in my letters of July 8 and July 30, 2002. In its notification, Clover compared its HiDHA® Tuna Oil to menhaden oil, 21 CFR Sec. 184.1472.

In GRN #109, specifications were provided not only for the HiDHA® Tuna Oil itself, but also for two products that Clover manufactures using HiDHA® Tuna

Piper Rudnick

Oil. Both products, HiDHA® Tuna Oil Powder and High Oil Loading Powder, are composed of HiDHA® Tuna Oil in combination with other suitable approved ingredients, all of which are listed in Table 3 of the notification. It is Clover's position that neither powder product requires a separate determination of its GRAS status in addition to the determination sought regarding HiDHA® Tuna Oil, as both powder products are otherwise composed entirely of GRAS or other approved substances.

Consequently, in answer to your first question regarding whether the manufacturing method described in the notification applies to the powder products, the answer is that it does. The manufacturing method described is the only method used to produce HiDHA® Tuna Oil and, as noted above, the powder products are manufactured through the addition of other suitable GRAS or other approved substances to the Tuna Oil.

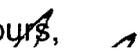
Your other question concerned Table 2, "Specifications for HiDHA® products." We apologize for the confusing footnotes to this table. The specifications provided are for the subject of the GRAS notification, HiDHA® Tuna Oil. Total fat is meant to denote the amount of total lipids in each of the items described. The last two columns provide information regarding the two powder products made using HiDHA® Tuna Oil:

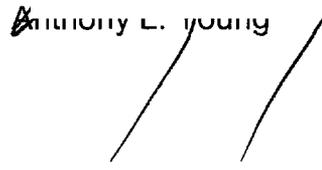
- HiDHA® Tuna Oil Powder contains approximately 25 percent HiDHA® Tuna Oil, but additional lipid is provided by hydrogenated palm oil (see Table 3); as a result, the percentage of total fatty acids that are DHA and EPA is slightly less than in pure Tuna Oil.
- High Oil Loading Powder is approximately 50 percent HiDHA® Tuna Oil and contains no other source of lipid (see Table 3), thus the DHA and EPA content as percentage of total fatty acids is the same as in HiDHA® Tuna Oil.

As noted, the GRAS notification concerns only HiDHA® Tuna Oil. Information about related products was provided only for information. The intent is that HiDHA® Tuna Oil and all products containing it will be used for the same purposes presently (or as amended in the future) allowed for Menhaden Oil and will be added to foods at levels such that the total added EPA+DHA from all sources will not exceed the levels permitted for added EPA+DHA from menhaden oil.

Piper Rudnick

Please direct any further questions to me at the e-mail address or telephone number above. Thank you in advance for your prompt consideration of this response.

Sincerely yours, 


Anthony L. Young

ALY/jjb
cc: Hamish Drummond
Managing Director
Clover Corporation Limited

James Heimbach, Ph.D.

000025