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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.

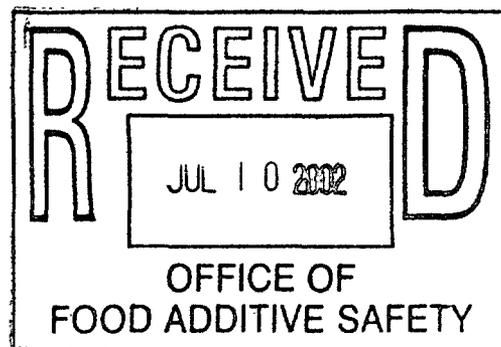
Michael T. Watson, Ph.D.

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Notice No. GRN 000097, Withdrawn on June 24, 2002 by Clover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

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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Notice No. GRN 000097, Withdrawn on June 24, 2002 by Clover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We are counsel to Clover Corporation Limited, North Sydney, Australia (Clover), the sponsor of the withdrawn GRAS Notification for tuna oil that is referenced above.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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