ORIGINAL SUBMISSION

March 18, 2016

GRN 000642

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

RE: "Refined Camelina Vegetable Oil" as GRAS Exemption Claim

I am attaching, in triplicate, the claim for exemption of camelina oil as Generally Recognized As Safe (GRAS) based on the format provided by FDA at their website in accordance with the Federal Register 62 FR 18937, April 17, 1997.

In accordance with the claims, I am attaching as an addendum the peer reviews of authorities in the food and medical industries sanctifying that camelina oil is safe for human consumption. This oil has a long association with humans and animals in diets stretching back to the neolithic period but was discarded when more more prolific and more agriculturally acceptable crops were adopted primarily in eastern and western Europe during the Industrial Age.

As an excellent source of omega-3 fatty acids, camelina has been accepted as a food oil in Europe and in Canada. If you have questions regarding this notice, please feel free to contact me.

Sincerely,

(b) (6)

Duane Johnson, PhD.
CamStar
tel. 406-261-5911
email: newcropper@outlook.com

GRAS EXEMPTION CLAIM FOR CAMELINA OIL

1. GRAS EXEMPTION CLAIM

1A. Claim of Exemption from the Requirement for Premarket Approval Pursuant to Proposed 21 CFR §170.36(c)(1) [62 FR 18938 (17 April 1997 (U.S. FDA))]

As defined herein, Refined Camelina Oil has been determined by CamStar Omega (**CamStar**) to be Generally Recognized as Safe (GRAS), which is consistent with Section 201(s) the *Federal Food, Drug, and Cosmetic Act*. This determination is based on scientific procedures as described in the following sections and on the consensus opinion of an independent panel of experts qualified by scientific training and knowledge to evaluate the safety of Camelina Oil under the conditions of intended use in food. Therefore, the use of Nutrition Company's *Refined Camelina Oil* in food as described is exempt from the premarket approval requirement [Section 409 of the *Federal Food, Drug, and Cosmetic Act (www.nutritioncompany.com.)]*.

Signed,
(b) (6)

March 18, 2016
Date

Dr. Duane Johnson
Corporate Research Director
CamStar, LLC

1B. Name and Address of Notifier

Dr. Duane Johnson
Corporate Research Director
CamStar, LLC
439 Grand Ave., Suite 118
Bigfork, MT 59911
Email: newcropper@outlook.com
Cell: 406-261-5911

1B. Common Name of the Notified Substance

Camelina Oil

1C. Conditions of Intended Use in Food

CamStar intends to market Camelina Oil as a food ingredient in the United States under the proposed food uses described in Table 1 at a use level of 3.0 g/serving. Camelina Oil is intended to be used as a replacement for other omega-3 oils and is not intended to be used in any meat or meat-containing products.

Table 1. Summary of the Individual Proposed Food-Uses and Use-Levels for Camelina Oil in the United States

Food Category	Proposed Food Use	Level [t]RACC	Use Level (%)
Baked Goods and Baking Mixes	Cookies (excluding low fat and dietetic)	3.0	10.0
Beverages and Beverage Bases	Meal Replacement Beverages	3.0	1.25
	Sports, Energy, and Isotonic Drinks	3.0	1.25
Breakfast Cereals	Oatmeal-based Instant and Regular Hot Cereals	3.0	5.45
Dairy Replacements	Imitation and Soy Milks	3.0	1.25
Fats and Oils	Salad Dressings (excluding mayonnaise, fat-free and low-fat types)	3.0	10.0
Grain Products and Pasta	Cereal and Granola Bars (excluding low-fat types)	3.0	7.5
	Energy, Meal Replacement, and Fortified Bars	3.0	7.5
Milk and Milk Products	RTD Flavored Milk and Milk Drinks (excluding fat- free types)	3.0	1.0
	Meal Replacement Beverages (milk-based)	3.0	1.25
	Yogurt Beverages[$]	3.0	1.5
	Yogurt (excluding fat-free types)	3.0	1.33
Processed Fruits and Fruit Juices	Fruit Flavored Drinks	3.0	1.25
	Fruit Juice	3.0	1.25
Processed Vegetables and Vegetable Juices	Fruit Smoothie Drinks	3.0	1.25
	Vegetable Juice	3.0	1.25
Snack Foods	Chips, Pretzels and Other Savory Snacks	3.0	10.0
Soft Candy	Nut-based Chocolate Confections	3.0	7.5
	Soft Candies	3.0	7.5
Soups and Soup Mixes	Dehydrated and Powdered Soup Mixes	3.0	38.13

Note: [t]RACC = Reference Amounts Customarily Consumed per Eating Occasion (21 CFR §101.12 - U.S. FDA, 2009); When a range of values is reported for a proposed food-use, particular foods within that food-use may differ with respect to their RACC.

[$]Food codes for yogurt beverages were not identified. Thus, codes representing milk containing acidophilus were used as surrogates.

1D. Basis for the GRAS Determination

Pursuant to 21 CFR §170.30, Camelina Oil has been determined by CamStar as GRAS on the basis of scientific procedures (U.S. FDA, 2009). This determination is based on publicly available data pertaining to the safety of Camelina Oil used in food and food products, as discussed herein and in the accompanying documents. Furthermore, a panel of experts who are qualified by scientific training and knowledge to evaluate the safety of Camelina Oil as a component of food have reviewed the literature and uniformly support this determination **[see Appendix 1, EXPERT PANEL LETTERS OF RECOMMENDATION CONCERNING THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF CAMELINA OIL FOR USE IN FOOD]**.

The Panel consisted of the following qualified scientific experts:

Sharon Goldberg, MD
President
Glow Health, P.A.
1065 Kane Concourse
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Bay Harbor Islands, FL 33154

Joerg Gruenwald, PhD
President
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Lothar Haegele, PhD
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1E. Availability of Information

The detailed data and information that serve as the basis for this GRAS determination will be provided to the United States Food and Drug Administration (FDA) upon request. Further information is available for the FDA's review and copying during business hours at the following address:

Dr. Duane Johnson
CamStar, LLC
439 Grand Ave., Suite 118
Bigfork, MT 59911

Should the FDA have any questions or require additional information, CamStar will gladly provide clarification and/or further information.

2. DETAILED INFORMATION ABOUT THE IDENTITY OF THE SUBSTANCE

2A. Identity

CamStar's Camelina Oil is an edible oil obtained from camelina (*Camelina sativa*), consisting of a mixture of triglycerides of which the major fatty acid components are oleic (min. 30%), linoleic (min. 34%), and linolenic (min. 32%) as shown in Figure 1. Camelina Oil is a bright yellow clear liquid at ambient temperature.

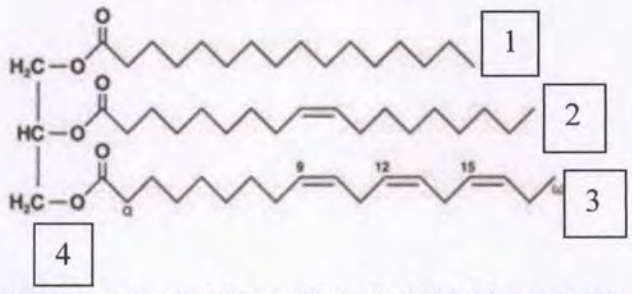
Common or Usual Name:	Camelina Oil
Chemical Name:	Not applicable
Chemical Abstracts Service (CAS) Number:	68956-68-3
Empirical Formula and Formula Weight:	Not applicable
Molecular Weight:	Not applicable: Variable
Structural Formula:	See Figure 2A.1 below.

The chemical structures of the major fatty acid components of Camelina Oil (oleic, linoleic, and linolenic acids) are presented in Figure 2A.1. A detailed summary of the fatty acid composition of Camelina Oil is presented in Table 2A.1.

Figure 2A.1. Major Fatty Acid Components of Camelina Oil (as Triacylglycerides [Triglycerides])

Triglyceride mixture, where R_{1_3} represent various fatty acids including: **Stearic Acid** - C18:0; **Oleic Acid** - 9-cis-octadenoic acid, C18:1 (*ω-9*); **Linoleic Acid** - 9-cis,12-cis-octadecadienoic acid, C18:2 (*ω-6*); and **Linolenic Acid** - 3-cis,9-cis,12-cis-octadecatrienoic acid; C18:3 c3,c9,c12 (*ω-3*)

Triacylglyceride Model



Note: 1. Saturated fatty acid; 2. Mono-unsaturated fatty acid (ω-9); 3. Highly unsaturated fatty acid (ω-9, 6, 3); and 4. Sugar alcohol backbone (glycerin)

The average Camelina Oil fatty acid profile is shown in Table 2B.1. In addition, Table 2B.2 lists aids and antioxidants that may be used in preparing Camelina Oil for commercial use. Such aids provide long-term shelf stability and are approved for use by the FDA.

Table 2B.1. The Average Camelina Oil Fatty Acid Profile

Fatty Acid Profile	Average Crude Oil of Two Replications (µg/g)
Palmitic Acid - C16:0	6.2
Palmitoleic Acid - C16:1	0.3
Stearic Acid - C18:0	2.7
Oleic Acid - C18:1 (ω-9)	28
Linoleic Acid - C18:2 (ω-6)	21.7
Linolenic Acid - C18:3	32.5
CLA (9-11[4];10-12)	1.3
Arachidic Acid - C20:0	1.5
Eicosatrienoic Acid - C20:3	0
Eicosenoic Acid - C20:1	1.8
Eicosadienoic Acid - C20:2	1.5
Eicosapentaenoic Acid - C20:5	0.5
Behenic Acid - C22:0	0.5
Docopentaenoic Acid - C22:1	1.1
Lignoceric Acid - C24:0	0.7
Nervonic Acid - C24:1	0.1
Total Saturated Fatty Acids	11.1
Total Monounsaturated Fatty Acids (ω-9)	31.3
Total Polyunsaturated Fatty Acids (ω-6, 9)	23.5
Total Highly Unsaturated Fatty Acids (ω-3, 6, 9)	33.0
Total C18 Trans Fatty Acids	0.7
Total CLA	1.3

Note: (KSU, Vet. Medicine, 2003, pers. comm.)

Table 2B.2. List of Processing Aids and Antioxidants Potentially Used in the Manufacture of Camelina Oil

Processing Aids Used in the Manufacture of Camelina Oil	Function/Manufacturing Step(s) at which Processing Aid is Used	Reference to Appropriate Use in Food Method of Analysis
Citric Acid	pH control agent	21 CFR §184.1033
Activated Carbon	Purification, deodorization, and decolorization	No specific regulations pertaining to activated carbon. However, it is an accepted aid in food oil manufacture (GRAS Notice GRN 000138 [U.S. FDA, 2004])
Filters (Cellulose)	Various separation steps throughout processing	21 CFR §177.2260
Tocopherols	Antioxidant	21 CFR §182.3890
Rosemary Extract	Antioxidant	21 CFR §182 20

Note: CFR = Code of Federal Regulation; GRAS = Generally Recognized as Safe (U.S. FDA, 2009)

The processes involved in the manufacture of Camelina Oil are conventional techniques employed by the fats and oils industry to improve the quality of the oil. They do not result in any chemical modification of the crude Camelina Oil. The manufacturing process is consistent with current Good Manufacturing Practices (cGMP).

2C. Product Specifications and Analysis

Camelina Oil is produced in accordance with cGMP, and to ensure a consistently safe product, CamStar has established food-grade specification parameters for the ingredient. These parameters comprise specifications for the physical appearance, purity, acid components, and specifications for potential chemical and microbiological impurities and contaminants. The chemical and microbiological specifications for Camelina Oil are presented in Table 2C.1. Analyses of three representative, non-consecutive lots confirm the material produced by the manufacturing process is consistent and complies with these product specifications.

Table 2C.1. Chemical and Microbiological Specifications for Camelina Oil

Parameter	Specification	Analytical Method
Appearance	Pale Yellow Liquid	Visual
Free Fatty Acids (as % oleic acid)	Max 1.0%	Titration method ISO 660
Peroxide Value	Max 10.0 meq02/kg	AOCS Cd 8b-90 (97)
Total Saturated Fatty Acids	Max 12%	High resolution capillary gas chromatography
Total Monounsaturated Fatty Acids	Min 24%	High resolution capillary gas chromatography
Oleic Acid (C18.1, ω-9)	Min 22%	High resolution capillary gas chromatography
Total Polyunsaturated Fatty Acids	Min 64%	High resolution capillary gas chromatography
Linolenic Acid (C18:2, ω-6)	Min 34%	High resolution capillary gas chromatography
Trans fatty acids	Max <0.1%	High resolution capillary gas chromatography
Lead (Pb)	Max 0.1 mg/kg	DIN EN 13805 / 14083 / Atomic absorption method
Arsenic (As)	Max 0.1 mg/kg	DIN EN 13805 / 14083 / Atomic absorption method
Total aerobic count	<1,000 cfu/g	ISO 4833
Yeasts	<10 cfu/g	ISO 7954
Molds	<10 cfu/g	ISO 7954
Escherichia coli	<10 cfu/g	ISO 16649-2
Salmonella	Absent in 25 g	ISO 6579
Enterobacteriaceae	<10 cfu/g	ISO 21528-2

Note: AOCS = American Oil Chemists Society; cfu = colony-forming units; ISO = International Standards Organization

2D. Stability

Camelina Oil is stable for a minimum of 18 months from the date of production, when stored unopened in dry conditions under an inert atmosphere (nitrogen) or in a dark container between temperatures of 10 to 20° C (50 to 60° F).

2E. Self-Limiting Levels of Use

The use of Camelina Oil is self-limiting based on the taste and shelf-life characteristics of the oil as well as rancidity (oxidation).

BASIS FOR GRAS DETERMINATION

3A. Introduction

To review the most up to date and relevant state of the science on Camelina Oil, a systematic literature search for published, peer-reviewed articles was performed using the Med-line Ovid, Cochrane library, and Web of Science databases. Articles published in English (or with an English abstract) from 1800 to 2016 with full texts available were searched using the terms "camelina oil" or "camelina sativa" or "omega-3 fatty acids" or "essential fatty acids." Inclusion criteria were: (a) studies describing the use of Camelina Oil in humans or animals and (b) at least one study outcome related to safety, efficacy, or toxicological evaluation of Camelina Oil.

The overriding conclusion from the review of the extant literature is that Camelina Oil is determined to be GRAS based on scientific procedures. The safety of Camelina Oil is based on an estimate of the probable consumption of Camelina Oil, as calculated using the most recent publicly-available survey of United States food consumption. In addition, Camelina oil has a long-documented history of human consumption, contains no ingredients of toxicological concern, and has no adverse effects at the stated usage levels.

A 13-week porcine (swine) toxicity study incorporating 15% Camelina Oil into the diet demonstrated no-observed-adverse-effect level (NOAEL). This NOAEL corresponded to a daily intake of approximately 8.9 or 10.2 g Camelina Oil/kg body weight/day for female and male swine, respectively (Ni Eidhin et al., 2003). Johnson et al. (2005) examined fingerling rainbow trout (7-9 cm in length) harvested after being fed for 2 weeks an equivalent soy-, camelina-, or fish-oil based diet. Body fat of harvested fish, analyzed by Montana State University investigators, demonstrated DHA and EPA levels from camelina oil and fish oil were not significantly different and both significantly superior to the soy-oil diet. This was attributed to bacterial conversion in the gut of fish from camelina DEA and EDA to DHA and EPA, respectively. Using a camelina meal with 7.7% Camelina Oil, Rajapakse (2015) found no detrimental effects in broiler chickens.

Data from human studies further support the conclusion gleaned from animal studies; that Camelina Oil is safe for animal and human consumption at the clearly defined usage levels. A randomized, controlled trial of Camelina Oil supplementation (30 g/day) in place of usual dietary oil, in a cohort of hypercholesterolemic Finnish adults, demonstrated no adverse effects. Camelina Oil was well-tolerated, and subjects showed no changes in blood glucose and insulin. Significant reductions in blood serum low-density lipoproteins were observed in the Camelina Oil group, further supporting the animal feeding studies that showed a favorable effect on lipids. This study demonstrated a therapeutic, lipid lowering effect of Camelina Oil (Karvonen et al., 2002). Sands et al. (2009) found Camelina Oil to be well-balanced nutritionally and useful in bread making.

The best historical evidence of Camelina Oil's importance comes from the mummified body of Tollund man, who died approximately in 4th century BC and was found in Denmark in 1950.

Zubr (1997) stated that "camelina has been used by humans as food since the Neolithic period and was a popular food in Europe by the Iron Age" (Knorzer, 1978). Camelina species are indigenous to the United States and Canada and were presumably spread across the continent by Native Americans as a ready food source (USDA/NRCS Plants Database: http://plants.usda.gov). Camelina was introduced to the United States in 1851 and verified as an agricultural crop in 1863 in South Carolina (Porcher, 1863). Health Canada has registered Camelina Oil as a food crop in Canada and expressed no objection to camelina as a food oil (Anon, 2010). Lastly, Camelina Oil is registered as a food oil in many European countries (Gupta, 2009).

These data were reviewed by a panel of experts, qualified by scientific training and knowledge, to evaluate the safety of Camelina Oil as a component of food. The panel concluded that proposed uses of Camelina Oil are safe and suitable and would be GRAS based on scientific procedures **[see Appendix 1, EXPERT PANEL LETTERS OF RECOMMENDATION CONCERNING THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF CAMELINA OIL, USE IN FOOD]** and that other qualified experts would concur with these conclusions. It is also CamStar's opinion that other qualified and competent scientists reviewing the same publicly-available toxicological and safety information would reach the same conclusion. A summary of these data is presented herein.

3B. Probable Consumption of Camelina Oil

3B.1 Estimated Intake of Camelina Oil under the Intended Conditions of United States Foods
As mentioned, Camelina Oil is intended for use in a variety of food products, including baked goods and baking mixes, beverages and beverage bases, breakfast cereals, dairy product analogs, fats and oils, grain products and pasta, milk and milk products, processed fruit and fruit juices, processed vegetables and vegetable juices, snack foods, soft candy, and soups and soup mixes, at a level of 3.0 g/serving. Camelina Oil is intended to be used as a replacement for other oils.

The consumption of Camelina Oil from all intended uses and use levels was estimated using the National Center for Health Statistics' (NCHS) 2005-2006 National Health and Nutrition Examination Surveys (NHANES) (CDC, 2006; USDA, 2009). Under the intended food use, 94.6% of the total United States population was identified as potential consumers of Camelina Oil. On an all-user basis, the mean intake of Camelina Oil in the total United States population from all proposed food-uses was estimated to be 8.9 g/person/day or 150 mg/kg body weight/day. The heavy consumer (90^{th} percentile) all-user intake of Camelina Oil by the total United States population from all proposed food-uses was estimated to be 17.8 g/person/day or 327 mg/kg body weight/day. Under the intended conditions of uses, the estimated intakes of Camelina Oil for all population groups are presented in Tables 3B.1.1 and 3B.1.2 on a per person and per kilogram body weight basis, respectively.

Table 3B.1.1. Summary of the Estimated Daily Intake of Camelina Oil from All Proposed Food-Uses in the United States by Population Group

Population Group	Age Group (Years)	Actual Number of Users	All-Person Consumption		All-User Consumption	
			Mean (g)	90th Percentile (g)	Mean (g)	50th Percentile (g)
Children	3 to 11	1,427	8.7	16.0	8.9	16.0
Female Teenagers	12 to 19	956	7.8	15.1	8.3	15.4
Male Teenagers	12 to 19	896	9.7	20.0	10.4	20.3
Female Adults	20 and Up	2,016	7.4	15.7	7.9	16.3
Male Adults	20 and Up	1,748	9 2	19.6	10.0	20.4
Total Population	All Ages	7,043	8.4	17.2	8.9	17.8

Note: (2005-2006 NHANES Data)

Table 3B.1.2. Summary of the Estimated Daily per Kilogram Body Weight Intake of Camelina Oil from All Proposed Food-Uses in the United States by Population Group

Population Group	Age Group (Years)	% Users	Actual # of Total Users	All-Person Consumption		All-User Consumption	
				Mean (mg/kg)	Percentile (mg/kg)	Mean (mg/kg)	90th Percentile (mg/kg)
Children	3 to 11	98.7	1,423	343	661	350	665
Female Teenagers	12 to 19	96 1	950	133	271	142	276
Male Teenagers	12 to 19	95.2	894	148	312	159	314
Female Adults	20 and Up	93.7	1,997	105	228	111	234
Male Adults	20 and Up	91.4	1,722	109	228	118	237
Total Population	All Ages	94.6	6,986	141	314	150	327

Note: (2005-2006 NHANES Data)

As mentioned, the estimated intakes of Camelina Oil under the intended conditions of use were calculated using recently published United States dietary consumption surveys (i.e., 2005-2006 NHANES; CDC, 2006; USDA, 2009), which include two 24-hour dietary recalls administered on 2 non-consecutive days. The surveys provide the most appropriate data for evaluating food-use and food-consumption patterns in the United States. However, it is well established that the length of a dietary survey affects the estimated consumption of individual users and that short-term surveys overestimate consumption over longer time periods (Anderson, 1988). Moreover, the calculations assume that all food products within a food category contain the ingredient at the maximum specified level of use. Therefore, the estimated intakes of Camelina Oil are over-estimates of anticipated actual consumption.

3B.2 Occurrence of Camelina Oil in the Diet and Background Dietary Intake

Camelina Oil is a traditional oil, first recognized as the primary vegetable oil in the Bronze Age by Romans as they invaded Germany. Its use as a vegetable oil in cooking, soap making, and as a lubricant increased as the Romans discovered it. It was also excellent as a massage oil and labeled by its current common name "Gold of Pleasure." Camelina seeds

have also been found in the food pouches of mummies recovered from Danish bogs, demonstrating wide appeal and approval by central and western Europeans. The development of the Industrial Age introduced oilseeds such as linseed flax, which provided a fiber used in cloth and sailcloth and oils used in paints and shellacs. Camelina Oil is derived from the seed of camelina (*Camelina sativa*). Camelina is native to all of Europe, Asia, and Scandinavia.

3C. Absorption, Distribution, Metabolism, and Elimination

No specific absorption, distribution, metabolism, and elimination (ADME) studies have been conducted on CamStar's Camelina Oil. However, data are available on the absorption, distribution, and metabolism of the component fatty acids from the literature. The general ADME properties of Camelina Oil are comparable to that of any omega-3 triglyceride. The definitive study by Ní Eidhin and colleagues entitled, *Effects of Dietary Camelina Oil on Fatty Acid Distribution, Serum Cholesterol and Triglycerides of Porcine Blood Lipids*, compared Camelina Oil, fish oil, and a control. This was a randomized and replicated feeding trial of 33 days duration. Fatty acid analysis of tissues and blood from porcine (swine) demonstrated that feeding Camelina Oil or fish oil resulted in an increase in omega-3 fatty acids and a concomitant decrease in omega-6 fatty acids (Table 3C.1). The most striking effects of Camelina Oil or fish oil intake were those on plasma eicosapentaenoic acid (EPA - C20:5, ω-3), which dramatically increased by all three experimental diets (Table 3C.1). Given the similarity of porcine and human lipid metabolism and data on the effects of ALA in humans, it is biologically plausible that daily ingestion of ALA from Camelina Oil would increase plasma omega-3 fatty acids, have beneficial effects on serum triglyceride concentrations, and likely have a favorable effect on cholesterol levels in humans.

Table 3C.1. Fatty Acid Effects during 33-Day Study of Swine

Intervention	Changes in Percent of Fatty Acids					
	LA	ALA	AA	EPA	DPA	DHA
Control	↑7.7	↓2.8	-	↑11.1	↑12.5	↓7.7
5% Fish oil	↓3.1	↓20.1*	↓63.3**	↑722.2***	↑25.0	↑190.0***
5% Camelina oil	↓17.4*	↑18.1	↓41.4*	↑220.0***	↑22.2	↑108.3**
10% Camelina oil	↓19.5*	↑31.3*	↓40.0*	↑260.0***	↑12.5	↓72.7**

Note: Values are percent for each dietary group. ↑ = increase, ↓ = decrease; *p<0.05, **p<0.01, and ***p<0.001; ALA = α-linolenic acid, C18:3 ω-3; AA = arachidonic acid, C20:4 ω-6; EPA = eicosapentaenoic acid, C20:5 ω-3; DPA = docosapentaenoic acid, C22:5 ω-3; and DHA = docosahexaenoic acid, C22:6 ω-3

The 5% fish oil diet contained 0.48% EPA accounting directly for the increase in plasma EPA levels due to fish oil ingestion. However, the Camelina Oil diets did not contain EPA, and the increase in plasma EPA on Camelina Oil ingestion must have been due to elongation and distortion of ALA *in vivo*. Serum cholesterol effects were also noted. They are illustrated in Table 3C.2.

Table 3C.2. Serum Cholesterol Effects during 33-Day Study of Swine

Intervention	Serum Cholesterol Concentration (mmol/L)		
	Day 0	Day 12	Day 33
Control	2.09 ± 0.19^{a}	1.94 ± 0.21^{a}	1.96 ± 0.18^{a}
5% Camelina oil	2.07 ± 0.21^{a}	2.01 ± 0.27^{a}	2.03 ± 0.26^{a}
10% Camelina oil	2.45 ± 0.21^{b}	2.46 ± 0.26^{b}	2.14 ± 0.35^{a}
5% Fish oil	2.08 ± 0.21^{a}	2.08 ± 0.18^{a}	2.20 ± 0.26^{a}

Note: Values are means ± standard deviation for each dietary group.
^{a,b}Values in the same column/row with different superscripts are significantly different ($p<0.05$).

Serum triglyceride concentrations were significantly reduced by the 5% and 10% Camelina Oil diets by 17.9% and 24.2% respectively, but not by the 5% fish oil diet (Table 3C.3).

Table 3C.3. Serum Triglyceride Effects during 33-Day Study of Swine

Intervention	Serum Triglyceride Concentration (mmol/L)		
	Day 0	Day 12	Day 33
Control	$0.52 \pm 0.15^{a,y}$	$0.49 \pm 0.17^{a,y}$	$0.55 \pm 0.12^{a,y}$
5% Fish oil	$0.46 \pm 0.11^{a,y}$	$0.47 \pm 0.12^{a,y}$	$0.46 \pm 0.07^{a,y}$
5% Camelina oil	$0.56 \pm 0.12^{a,y}$	$0.52 \pm 0.08^{a,y}$	$0.46 \pm 0.18^{a,z}$
10% Camelina oil	$0.66 \pm 0.32^{a,y}$	$0.62 \pm 0.14^{b,y}$	$0.50 \pm 0.14^{a,z}$

Note: Values are means ± standard deviation for each dietary group. ^{a,b}Values refer to significant differences at the morning sampling ($p=0.05$). ^{y,z}Values refer to significant differences at evening sampling.

Hematological Analysis

In the porcine study of Ní Eihdin et al. (2003), the 5% Camelina oil, 10% Camelina oil, and 5% fish oil diet did not significantly alter white cell count, red cell count, hemoglobin, packed cell volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, or platelet count in blood (data not shown here).

Fatty Acid Analysis in Ewe's Milk

Studies by Szumacher-Strabel et al. (2014) and Puls (2015) showed camelina sativa cake (CSC) is a rich source of unsaturated fatty acids and may improve the energy value of a diet and also increase the unsaturated fatty acid content in milk in the case of ruminants. Effects of basal diet (control), basal diet plus 30 g/kg of CSC in dietary dry matter (DM), and basal diet plus 60 g/kg of CSC in dietary DM on milk production and the fatty acid composition of ewe's milk showed particular emphasis on the monoenes and conjugated isomers of linoleic acid content (CLA). In addition, CSC supplementation resulted in elevated concentration of total monounsaturated fatty acids, an increase in monounsaturated fatty acids in the trans configuration, and an increase in total polyunsaturated fatty acid concentration. Total saturated fatty acid concentration was decreased.

Milk from CSC-supplemented ewes was characterized by increased levels of beneficial nutritional factors, including mono- and omega-3 polyunsaturated fatty acids, and was also lower in atherogenic and thrombogenic indices. Taking into consideration all the obtained results and recommended fat concentrations in a daily ruminant ration, Szumacher-Strabel et al. (2014) recommended supplementing a dairy ewe's diet with 30 g/kg DM of CSC in practice. Studies by Pilgeram et al. (2006) at the University of Idaho have found milk production per cow increased by 20% after an initial butterfat decline with diet change. Once adapted, the cows produced normal butterfat percentage with an increased omega-3 content. Similar results in lactating dairy cows were reported by Halmenies-Beauchant-Fillena et al. (2011), where omega-3 content of milk from Camelina Oil-fed cows were 10-fold higher than soy-oil fed cows.

Poultry Studies

In a 13-week poultry toxicity study (unpublished data from the University of Georgia), the highest level studied for CamStar's Camelina Oil product, 15% mixed into the diet was established as the NOAEL. This NOAEL corresponded to a daily intake of 8.9 and 10.2 g Camelina Oil/kg body weight/day for female and male chickens, respectively. Aziza, Quezada, and Cherian (2010a) fed broilers camelina meal at 10%, which led to over 2.5-fold increases in omega-3 fatty acid of white and dark meat. No difference was found in final body weight. Aziza, Quezada, and Cherian (2010b) found broiler feeding at 10% camelina meal led to: (a) a >1.5-fold increase in γ-tocopherols in the thigh meat; (b) an increase in thigh meat antioxidant activity; and (c) reductions in thiobarbituric acid reactive substances in the meat during storage and cooking. Cherian, Campbell, and Parker (2009) found layer feeding camelina meal at 10% led to over 8-fold increase in omega-3 fatty acids in the eggs. Camelina meal at low levels (5 and 10%) did not lead to any changes in egg production or egg quality. Addition of camelina at higher levels (15%) led to reductions in egg production, yolk fat, and yolk size. No effect on egg weight was noted. Pilgeram et al. (2007) found similar results. Layers fed 15% camelina meal containing 12% oil in diets showed no adverse effect on bird health or egg production. Over 140 mg of α-linolenic acid were observed in eggs.

Cherian et al. (2009) pointed out that consuming 1 egg could provide over 140 mg of omega-3 fatty acids and 100 g of thigh meat could provide 0.9 mg of omega-3 fatty acids. In addition, the meal could also enrich food products with tocopherols and other phenolic compounds (Aziza, Quezada, & Cherian, 2010b). Feeding flax to broiler birds is associated with negative effects on performance (Ajuyah et al., 1991; Gonzalez & Leeson, 2001). Flax is also approximately twice the price of wheat and maize. Therefore, camelina can be used to reduce feeding costs, while increasing omega-3 fatty acids and other functional nutrients in animal food lipids without affecting bird growth. This is justified by the 1.7 fold increase in γ-tocopherols and antioxidant activity in the thigh meat of camelina meal-fed birds (Aziza, Quezada, & Cherian, 2010b). While assessing sensory qualities of meat from birds fed camelina meal, Ryhanen et al. (2007) reported that inclusion of meal had no adverse effect on meat taste, juiciness, or tenderness. Therefore, inclusion of camelina meal rich in bio-active compounds may prove to be beneficial for providing omega-3 fatty acids, while reducing oxidative stress associated with omega-3 polyunsaturated fatty acid enrichment.

Cherian et al. (2009) noted that consuming a 100 g portion of dark or white meat from birds fed 10% camelina meal could provide between 0.88 and 0.45 mg/100 g of omega-3 fatty acids, when

compared with 0.29 to 0.14 mg/100 g from birds fed a maize-soybean-based diet. Pekel et al. (2009) also found meat from camelina-fed birds was higher quality than flax-fed chickens.

Rokka et al. (2002) fed camelina seed oil to hens and these researchers reported that inclusion of Camelina Oil had no effect on the sensory attributes (smell and taste) of chicken eggs.

3D. Toxicological Studies

Human Studies

Human studies are limited. To the best of our knowledge, the only published data is a study conducted in Finland by Karvonen et al. (2002). This novel study stimulated research on the health benefits of Camelina Oil. Camelina Oil is a good source of α-linolenic acid. The proportion of α-linolenic acid in serum fatty acids is associated with a risk of cardiovascular diseases such as heart attack and stroke. Karvonen et al. (2002) studied the effects of Camelina Oil on serum lipids and on the fatty acid composition of total lipids in comparison to rapeseed and olive oils in a randomized, parallel, double-blind setting. Sixty-eight hypercholesterolemic subjects aged 28 to 65 years were randomly assigned after a 2-week pretrial period to 1 of 3 oil groups: Camelina Oil, olive oil, or rapeseed oil. Subjects consumed daily 30 g (actual intake 33 mL) of test oils for 6 weeks. In the camelina group, the proportion of α-linolenic acid in the fatty acids of serum lipids was significantly higher ($p<0.001$) compared to the 2 other oil groups at the end of the study (2.5 times higher than the rapeseed oil group and 4 times higher than the olive oil group). The proportions of 2 metabolites of α-linolenic acid (eicosapentaenoic and docosapentaenoic acids) increased and differed significantly in the camelina group compared to the other two groups. At the end of the intervention, the serum low-density lipoprotein cholesterol concentration decreased significantly by 12.2% in the Camelina Oil group, by 5.4% in the rapeseed oil group, and by 7.7% in the olive oil group. In conclusion, Camelina Oil significantly elevated the proportions of α-linolenic acid and its metabolites in the serum of mildly or moderately hypercholesterolemic adults. Camelina Oil's serum cholesterol-lowering effect was comparable to that of rapeseed and olive oils.

3E. Summary and Basis for GRAS Conclusion

The GRAS determination for the use of Camelina Oil as a food ingredient is based on scientific procedures in both animal and human studies. Camelina Oil is proposed for use as an ingredient in baked goods and baking mixes, beverages and beverage bases, breakfast cereals, dairy product analogs, fats and oils, grain products and pasta, milk and milk products, processed fruit and fruit juices, processed vegetables and vegetable juices, snack foods, soft candy, and soups and soup mixes, at a level of 3.0 g/serving. Under the intended conditions of use, the estimated all-user mean and 90^{th} percentile intakes of supplemental Camelina Oil in the total population are 8.9 and 17.8 g/day, respectively (150 and 327 mg/kg body weight/day, respectively).

Camelina Oil is produced in accordance with cGMP and meets appropriate food-grade specifications. Camelina Oil is produced from cold-pressed camelina seed that is subjected to refining through purification and addition of antioxidants. The resulting product consists of a mixture of triglycerides of which the major fatty acid components are oleic, linoleic, and linolenic acid. CamStar has established chemical and microbiological specifications consistent

with other food-grade oils and their derivatives. Lot samples are routinely evaluated to verify compliance with the specifications.

The safety of Camelina Oil under the intended conditions of use is supported by the available toxicological animal and human studies. While human testing is limited, animal studies have shown no issues different from any other GRAS vegetable oil. In fact, Camelina Oil has been used for over 5,000 years as a dietary oil by humans without negative effects. It continues to be used today, and a brief review of the internet shows Camelina Oil being sold in the United States by at least 15 companies, many of which sell indirectly in health food stores. Similarly, at least 5 companies are selling Camelina Oil over the internet and in stores to support the health of dogs and horses. Additionally, Health Canada's review of the evidence determined that Camelina Oil has no food safety concerns and certified Camelina Oil as safe for use as a food since 2010 (Anon, 2010). Finally, Camelina Oil is registered as a food oil in many European countries (Gupta, 2009).

The data provided support CamStar's conclusion that the consumption of Camelina Oil under the intended conditions of use would not be expected to cause adverse effects. In fact, the data indicate that the use of Camelina Oil has several beneficial effects for human health: (a) increasing serum EPA and DHA fatty acid levels; (b) lowering of triglycerides relative to fish oil; (c) a lower cholesterol content when compared to fish oil; and (d) superior natural antioxidant content when compared to flax oil.

The Expert Panel convened on behalf of CamStar, independently and collectively, critically evaluated the data and information summarized above and concluded that the proposed use of Camelina Oil, produced consistently with cGMP and meeting appropriate food grade specifications described herein, is safe and suitable. Furthermore, the Expert Panel unanimously concluded that the intended uses of Camelina Oil are Generally Recognized as Safe (GRAS) based on scientific procedures. It is also CamStar's opinion that other qualified and competent scientists reviewing the same publicly-available toxicology and safety information would reach the same conclusion.

Based on scientific procedures, Camelina Oil is GRAS under the intended condition, i.e., use as a food ingredient described herein. Therefore, Camelina Oil is exempt from the definition of a food additive and thus may be marketed and sold for the uses designated above in the United States without the promulgation of a food additive regulation under 21 CFR.

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Appendix 1. Expert Panel Letters of Recommendation

Sharon Goldberg, MD
Glow Health, P.A.
1065 Kane Concourse, Suite 200
Bay Harbor Islands, FL 33154

January 7, 2016

Dr. Duane Johnson
Corporate Research Director
BigSky Star Omega, LLC
P.O. Box 115
Bigfork, Montana 59911

RE: GRAS exemption claim for camelina oil

Dear Dr. Johnson,

I have reviewed the scientific evidence on camelina oil and fully support your application for GRAS exemption for camelina oil for the intended use in foods. As a board certified internal medicine physician with extensive training and clinical experience in medical nutrition therapy and functional medicine, I am a qualified expert in the field of clinical nutrition. My conclusion that camelina oil is safe for the intended use in food is based on several factors. First, camelina oil has a clear, documented, longstanding history of human consumption, primarily as a food oil, without evidence of untoward effects. Second, my review of the literature, including but not limited to the 2002 Karvonen study, showed no adverse effects from daily camelina oil for 6 weeks. Third, the review of numerous animal studies further supports the beneficial effects of camelina oil on various outcomes.

Given the growing body of literature that supports the health benefits of omega 3 fatty acids in the human diet, with the concomitant pollution of our oceans and depletion of fish stocks, it is very important to consider plant based omega 3 sources such as *Camelina sativa*.

Sincerely,

(b) (6)

Sharon Goldberg, MD, DTM&H

Herbalist & Doc
Gesundheitsgesellschaft mbH

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Dr. Duane Johnson
Corporate Research Director
BigSky Star Omega, LLC
P.O. Box 115
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Dear Dr. Johnson,

As you know, I am a bio-medical researcher with over 35 years of experience, and I have particular expertise in herbal medicines and dietary supplements and I am also Expert Member of the USP Committee on Botanical Dietary Supplements and Herbal Medicines and author of the PDR for Herbal Medicines.

Based upon my review of the existing literature and the historical use of *Camelina sativa* by many societies and cultures (including a brought European and German tradition), I am in full support of this proposal to request GRAS exemption status from the United States Food and Drug Administration (FDA) for the use of camelina oil in foods and dietary supplements. Camelina oil has been consumed safely by humans for a very long period of time, and it has also been utilized as a feed source for livestock. Although market awareness of its potential has been relatively low in modern times, environmental and financial factors, along with its incredible nutrient profile, provide the opportunity to elevate it to a new and significant status.

Additionally, the FDA has already approved its use as a food for cattle and chickens, and the data collected on humans show no adverse effects. The ability of camelina oil to provide a better, less contaminated source of omega 3 fatty acids, compared to fish sources, makes it a very attractive addition to the food and dietary supplement industry. Thus, I can conclude that camelina oil is not only safe for human consumption, but may provide an ideal oil composition, just what our modern societies are waiting for.

Please do not hesitate to contact me if you need any additional information.

Best Regards

(b) (6)

Joerg Gruenwald, PhD
President

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Geschäftsführer:
Dr. Jörg Grünwald
Christof Jänicke

Amtsgericht
Berlin – Charlottenburg
HRB 61 711

X-Lab Biotech (S) Pte. Ltd.

January 13, 2016

Dr. Duane Johnson
Corporate Research Director
BigSky Star Omega, LLC
P.O. Box 115
Bigfork, Montana 59911

Dear Dr. Johnson:

As you are aware, I have over 35 years of experience developing a micellization biotechnology for a whole host of applications, including foods, dietary supplements, medications, drinks, cosmetics, and agricultural products. I have successfully created a technology that enhances the bioavailability and effectiveness of any active ingredient, and I have worked with organic and inorganic molecules in combination with saccharides, amino acids, and fatty acids, among others. Particular to this letter of support, I am an expert formulator in applying nutrients in a clinical setting that are enhanced with my biotechnology to deliver a high level of efficacy. With that said, I provide my unequivocal support for your submission to the United States Food and Drug Administration for a GRAS approval and waiver for the use of *Camelina sativa* in food and dietary supplements. Based on the current scientific literature showing no adverse side effects in human consumption, the historical use of camelina oil both as a food and as a nutrient source for livestock, and the prior approvals of FDA for the use of camelina oil for food for animals, I am certain that camelina oil should be included on the GRAS list. In addition, having a very dense nutrient profile, e.g., a high level omega 3 fatty acids, tocopherols, such as vitamin E, and other antioxidants, camelina oil is a very favorable option for consumers who are concerned with the problems associated with fish oil as an omega 3 fatty acid source, e.g., heavy metal contamination and rancidity. Camelina oil's superior growing season and input characteristics further enhance its overall market potential. Therefore, I am very happy to support your application for camelina oil to receive GRAS approval and will provide any additional technical and scientific support you may require. Let me know if I can assist you further.

Best regards,

(b) (6)

Dr. Lothar Haegele
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January 13, 2016

Dr. Duane Johnson
Corporate Research Director
BigSky Star Omega, LLC
P.O. Box 115
Bigfork, Montana 59911

Dear Dr. Johnson:

As you know, I am a clinical researcher with over 20 years of experience, and I have particular expertise in clinical nutrition and dietary supplements. Based upon my review of the existing literature and the historical use of *Camelina sativa* by many societies and cultures, I am in full support of this proposal to request GRAS exemption status from the United States Food and Drug Administration (FDA) for the use of camelina oil in foods and dietary supplements. Camelina oil has been consumed safely by humans for a very long period of time, and it has also been utilized as a feed source for livestock. Although market awareness of its potential has been relatively low in modern times (since the 1940s), environmental and financial factors, along with its incredible nutrient profile, provide the opportunity to elevate it to a new and significant status. Additionally, the FDA has already approved its use as a food for cattle and chickens, and the data collected on humans show no adverse effects. The ability of camelina oil to provide a better, less contaminated source of omega 3 fatty acids, compared to fish sources, makes it potentially a very attractive addition to the food and dietary supplement industry. Thus, I conclude that camelina oil is not only safe for human consumption, but may provide the most ideal oil currently known to mankind.

Please do not hesitate to contact me if you need any additional information.

Best Regards,

(b) (6)

John E. Lewis, PhD
Associate Professor

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM
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TATJANA RUNDEK, MD, PhD
Professor of Neurology and Public Health Sciences
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January 21, 2016

Dr. Duane Johnson
Corporate Research Director
BigSky Star Omega, LLC
P.O. Box 115
Bigfork, Montana 59911

Dear Dr. Johnson,

I am writing to you in full support of your proposal to request GRAS exemption status for the use of camelina oil in foods and dietary supplements from the US Food and Drug Administration (FDA).

As a clinical-translational scientist recognized by the NIH and other professional organizations and with over 25 years of experience in research in the areas of cerebrovascular disease and metabolic and nutrition physiology, I believe I am qualified to support this application based on my expertise, critical review of the existing scientific literature, and the historical use of *Camelina sativa* as a component of food. In review of publicly available toxicology and safety information, in my opinion camelina oil that is produced consistently with cGMP and meets appropriate food grade specifications is safe and suitable for human consumption.

Camelina oil has been consumed safely for a long period of time. The FDA has already approved the use of camelina oil as a food for cattle and chickens, which has been proven safe. In humans, camelina oil is also safe and may have great potential for health benefits. As a good source of α-linolenic acid, camelina oil may lower the risk of cardiovascular disease and stroke, which are the leading causes of death and disability worldwide. The health benefits of camelina oil seem to be attributed to its remarkable effect on lowering serum LDL cholesterol. This effect of camelina oil in foods would have a great public health impact.

If you need additional information please do not hesitate to contact me. Thank you.

Kind regards.

(b) (6)

Tatjana Rundek, MD, PhD, FAHA, FANA

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Miami, FL 33136

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UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

January 25, 2016

Dr. Duane Johnson
Corporate Research Director
BigSky Star Omega, LLC
PO Box 115
Bigfork, Montana 59911

Dear Dr. Johnson,

I am an Internist at the University of Miami Miller School of Medicine, in practice for over 20 years. I am the Medical Director of the Executive Health program, where my clinical practice is focused on wellness, prevention and nutrition. My specific area of interest for research is in exercise physiology and nutrition.

I have reviewed the literature on Camelina sativa, and am in full support of the request GRAS exemption status from the United States Food and Drug Administration for the use of camelina oil in foods and dietary supplements. Reviews of its historical use show that it has been used in various cultures for years. It has been safely consumed by both humans and as feed for livestock. Camelina oil has been shown to have a robust nutrient profile. In fact, it has already been approved by the FDA as food for cattle and chickens.

Camelina oil can provide us with a rich source of omega 3 fatty acids, without the worry of contamination that fish sources now carry. It is a very exciting potential addition to the food and dietary supplement industry. After a literature review, I believe that camelina oil is both safe for human consumption and is a tremendous source of omega 3 oils for the human diet.

Sincerely,

(b) (6)

Judi M. Woolger MD, FACP
Medical Director, Executive Health
University of Miami Miller School of Medicine

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LectinLabs · LTD

February 12, 2016

Dr. Duane Johnson
Corporate Research Director
CamStar, LLC
P.O. Box 115
Bigfork, MT 59911

Dear Dr. Johnson:

As you are aware, I am a scientist and business executive with over 27 years of experience in microbiology, glycobiology, and infectious diseases. I also have received multiple patents for applications utilizing complex carbohydrate receptors, bacterial toxins, and lectins; and, I have published a significant amount of research on similar topics. I have a significant research background in basic and clinical science and in various roles in corporate and academic environments.

Based upon my review of your GRAS notification to the United States Food and Drug Administration (FDA) for *Camelina sativa* for use in foods, I completely support this proposal. Based on the scientific literature, primarily in animals, and what humans know in recorded human history regarding Camelina's use, it is reasonable that camelina oil is safe and beneficial oil for current and future human consumption. Additionally, Health Canada certified camelina oil as a food there and many countries in Europe have done the same. Additionally, FDA has already certified camelina's use for livestock food. What data that has been reported in humans, do not show any deleterious side effects.

Camelina provides an opportunity to shift the omega-3 fatty acid market from one based heavily on fish oil, which has environmental problems with contamination and depletion of fish stocks. Camelina seed has a promising growing profile and has great potential to provide consumers with a less-contaminated alternative to fish oil. In total, the overall profile of Camelina oil makes it a potential powerhouse for the food industry. Thus, I fully support this notification from my professional experience and perspective.

Please let me know if you need to discuss this application further.

Sincerely,

(b) (6)

Howard Krivan, Ph.D.
President and Chief Science Officer
Lectin Labs, Ltd.
Carson City, NV

Adjunct Professor
Graduate School of Management & Technology
Program in Biosecurity & Biodefense
University of Maryland University College
Adelphi, MD

SUBMISSION END