



GRAS Notice (GRN) No. 437

<http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm>

ORIGINAL SUBMISSION

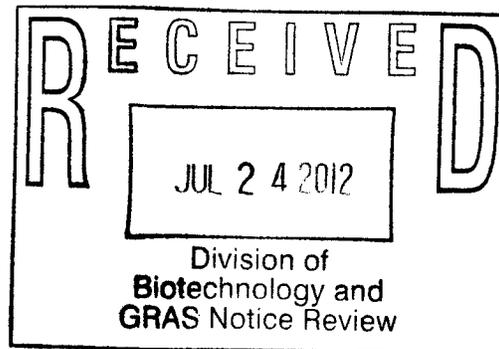
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July 19, 2012

Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Food Additive Safety (HFS-255)
5100 Paint Branch Parkway
College Park, MD 20740-3835



Attention: Dr. Mary D. Ditto

Re: GRAS Notification – Oat Beta-Glucan

Dear Dr. Ditto:

On behalf of Garuda International, Inc. of Exeter, CA, we are submitting a GRAS notification for B-CAN™, Garuda's oat-derived beta-glucan, for FDA review. Three copies of the subject GRAS notification are provided.

If additional information or clarification is needed as you and your colleagues proceed with the review, please feel free to contact me *via* telephone or email.

We look forward to your feedback.

Sincerely,

(b) (6)

Robert S. McQuate, Ph.D.
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Enclosure: GRAS Notification for Oat Beta-Glucan (3 copies)

Xc: R. Matkin, Garuda International, Inc.

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GRAS ASSESSMENT

of

OAT β -GLUCAN – B-CAN™

Food Usage Conditions for General Recognition of Safety

for

**GARUDA INTERNATIONAL, INC.
Exeter, CA**

Evaluation By

Robert S. McQuate, Ph.D.
Madhusudan G. Soni, Ph.D., FACN, FATS

July 19, 2012



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I. GRAS EXEMPTION CLAIM

A. Claim of Exemption from the Requirement for Premarket Approval Pursuant to Proposed 21 CFR 170.36(c)(1)¹

Garuda International, Inc. has determined that its oat β -glucan, meeting the specifications for B-CAN™ as described in Table 1, is Generally Recognized As Safe (GRAS) in accordance with Section 201(s) of the Federal Food, Drug, and Cosmetic Act. Garuda International made this GRAS determination based on scientific procedures in concert with an appropriately convened panel of experts who are qualified by their scientific training and experience. This finding is based on scientific procedures as described in the following sections, and the evaluation accurately reflects the conditions of the intended use of this substance in foods.

Signed:

(b) (6)

Robert S. McQuate, Ph.D.
GRAS Associates, LLC
20482 Jacklight Lane
Bend, OR 97702-3074

Date:

July 19, 2012

B. Name & Address of Notifier

Garuda International, Inc.
P. O. Box 159
Exeter, CA 93221

As the notifier, Garuda International, Inc. (hereinafter referred to as "Garuda") accepts responsibility for the GRAS determination that has been made for oat β -glucan as described in the subject notification; consequently, its oat β -glucan as described herein is exempt from pre-market approval requirements for food ingredients.

C. Common Name & Identity of Notified Substance

Oat β -glucan; oat bran concentrate; the commercial or trademarked name for Garuda's oat β -glucan is B-CAN™; also see Sections II.B and II.C.

¹ See 62 FR 18938 (17 April 1997) which is accessible at <http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/ucm083058.htm>.

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D. Conditions of Intended Use in Food

Oat β -glucan is intended to be added to the following food categories at levels yielding 0.75 to 3.0 g of β -glucan per serving: bars; beverages; breads, whole grain and specialty; breakfast cereals; cookies, lite; crackers, reduced fat; gravy and sauces, lite; instant rice; macaroni products; muffins, reduced fat; salad dressings, lite; snack chips, reduced fat; soups; tomato-based sauces; tortillas and taco shells; vegetarian patties/crumbles; yogurt, reduced fat; and medical foods.

Foods that are intended for infants and toddlers, such as infant formulas or foods formulated for babies or toddlers, and meat and poultry products are excluded from the list of intended food uses for the subject oat β -glucan.

E. Basis for GRAS Determination

Pursuant to 21 CFR 170.30, oat β -glucan has been determined to be GRAS on the basis of scientific procedures as discussed in the information provided below.

F. Availability of Information

The data and information that serve as the basis for this GRAS notification will be sent to the US Food and Drug Administration (FDA) upon request or will be available for review and copying at reasonable times at the offices of GRAS Associates, LLC, located at 20482 Jacklight Lane, Bend, OR 97702-3074.

II. DESCRIPTION OF NOTIFIED SUBSTANCE

A. Oat β -Glucan Background Information

Oats contain a form of soluble fiber that is identified as oat β -glucan. This soluble fiber is particularly concentrated in the outer layers of the grain. In recent years, the effect of β -glucan on cholesterol has gained significant attention, and much of the research into the cholesterol lowering activity of soluble fiber has centered on oat β -glucan. Originally, it was thought that soluble fiber can form viscous gels and thus can be easily fermented by colonic microflora. Subsequent research has revealed that solubility does not reliably predict the physiological effects of fiber. However, the terms "soluble" and "insoluble" fiber are still commonly used by scientific and regulatory committees.

In 1997, the Food and Drug Administration (FDA) approved the health claim on the association of soluble fiber from rolled oats and reduced risk of heart disease (21 CFR 101.81) (62 FR 3584, January 23, 1997). For this claim, FDA (1997) recognized that β -glucan (soluble fiber) was the primary component of whole oat products in influencing serum lipid levels. The agency stated that β -glucan plays a significant role in the relationship between whole grain oats and the risk of coronary heart disease (CHD). This conclusion was based on two major findings:

- a dose response between the level of β -glucan soluble fiber consumed and the level of reduction in blood total- and LDL-cholesterol, and
- β -glucan intakes of 3 g or more per day were effective in lowering serum lipids.

Following this initial health claim approval by FDA, manufacturers have attempted to market β -glucan- containing products to consumers.

B. Chemical Name, Common Name & CAS Number of Notified Substance

β -D-Glucan; (1-3), (1-4)- β -D-Glucan; and/or β -Glucosylglucan. The product is composed mainly of β -glucan. As reported in Section I.C., oat β -glucan is the common name of the notified substance, and B-CAN™ is the commercial name of the subject material for which the GRAS evaluation has been undertaken.

As discussed more fully in the following section, oat β -glucan products primarily containing $\geq 70\%$ β -glucan will be marketed under the trade name B-CAN™. Additionally, product containing $\geq 55\%$ β -glucan will also be marketed. There is a CAS Registry Number 9041-22-9 allocated to β -glucan that applies to β -glucan of any origin (e.g., barley, oat, mushroom, yeast, etc.).

C. Chemical Composition

Oat β -glucan consists of polysaccharides of unbranched, linear, mixed-linkage (1-3), (1-4)- β -D-glucans. Oat and barley derived β -glucans are reported to contain approximately 70% (1-4) linkages and 30% (1-3) linkages (Woodward and Fincher, 1983; Saulnier et al., 1994; FDA, 2011). Typically, blocks of three or four (1-4)-linked β -glucosyl units are connected by (1-3) linkages. Oat β -glucan appears to consist of higher tetrasaccharide and fewer trisaccharide building blocks and may have a higher molecular weight than β -glucan derived from barley. Wheat β -glucan contains even more trisaccharides compared to barley β -glucan. In other words, the composition of β -glucans from oat, barley and wheat form a continuum (FDA, 2011). However, the respective differences are rather small and are unlikely to result in physiological differences (FDA, 2011).

D. Method of Preparation of B-CAN™

Garuda produces its B-CAN™ by utilizing cleaned oat bran which is blended with hot water and given sufficient time to extract the water-soluble components. The insoluble materials are separated by filtration and are discarded. The solution that contains the oat bran solubles is treated with food-grade α -amylase enzyme to hydrolyze the oat starch, thereby converting it into glucose to aid in the separation. Additional filtration is employed to remove any remaining insoluble materials. The remaining liquid undergoes vacuum concentration.

As depicted in Figure 1, food-grade ethanol is added to the concentrate to precipitate the β -glucan from solution. The excess liquid is decanted, and the ethanol recovered. Centrifugation is employed to remove additional liquid from the precipitated β -glucan concentrate. Residual solvent

is removed from the concentrate---along with enzyme deactivation and additional product sterilization---by means of heat drying under vacuum.

The resulting dried concentrate is screened to particle size specifications prior to being passed through rare earth magnets and subsequently being packaged under hygienic conditions. QC sampling is conducted during the screening and packaging process.

Garuda's manufacturing process utilizes enzymes and processing aids that all comply with Food Chemicals Codex specifications.

E. Finished Product Specifications & Physical Characteristics

Food grade specifications for Garuda's oat β -glucan (B-CAN™) are presented in Table 1. Typically, the β -glucan content of B-CAN™ is $\geq 70\%$. B-CAN™ is a beige to light gray/brown colored powder. Analytical results from five non-consecutive lots are provided in the Appendix. B-CAN™ is manufactured using the amylase enzyme followed by extraction with ethanol. The analytical results found in the Appendix demonstrate that B-CAN™ meets the designated specifications.

F. Exposure Estimates

1. Current Consumption of Oat β -Glucan

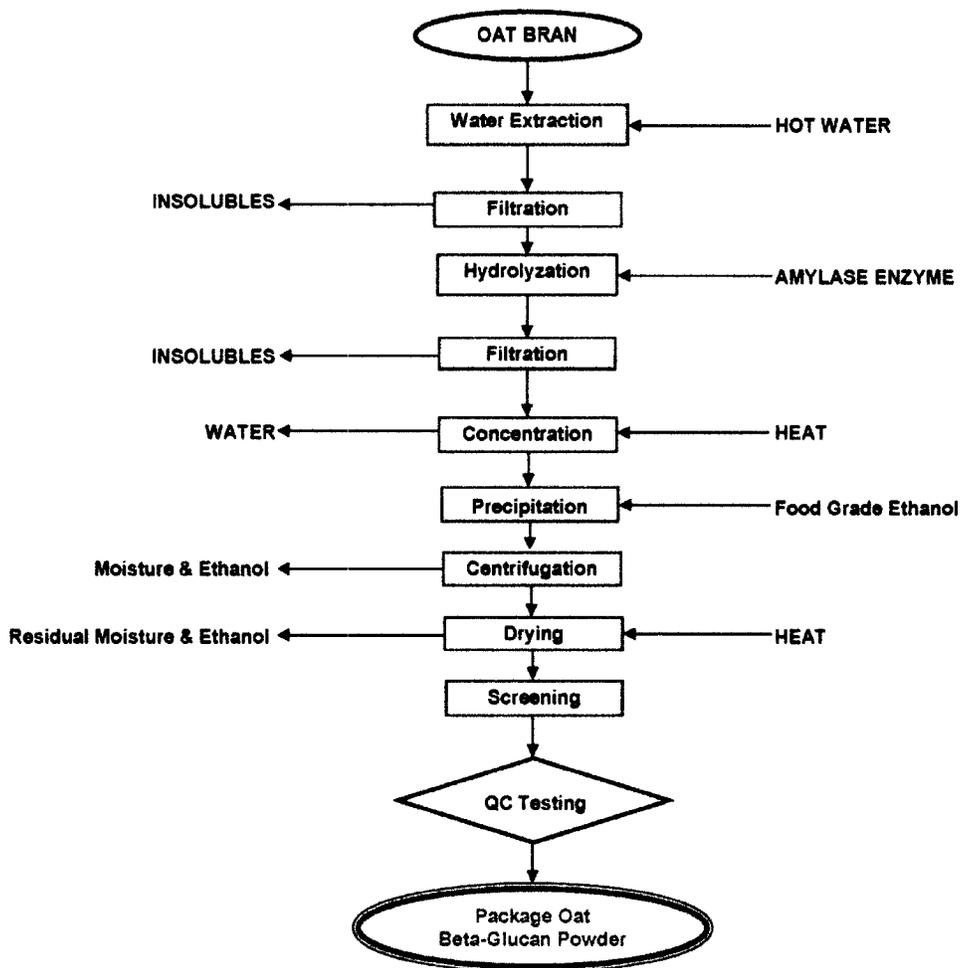
Based on the available information, no specific numbers could be found on the pre-existing exposure to cereal β -glucan. However, by reviewing substantiation of health claims described under 21 CFR 101.81 (FDA, 1997) for soluble fiber from certain foods and risk of coronary heart disease, it was noted that a daily intake of 3 g or more per day of β -glucan soluble fiber from either whole oats or barley, or a combination of whole oats and barley, was required. Hence, it can be estimated that a diet aiming to reduce the risk of coronary heart disease provides at least 3 g β -glucan/day. Given that oats and barley have a β -glucan content of on average 5 and 7%, respectively (Peterson et al., 1995; Oscarsson et al., 1996; Izydorczyk and Dexter, 2008), it can be calculated that a serving of 50 g whole grain oat or barley provides 2.5 and 3.5 g β -glucan, respectively.

In a recent GRAS notice on barley β -glucan (FDA, 2011), available information on background consumption of oat β -glucan is summarized. This information indicates that oat-derived β -glucan concentrates, including oatrim with a β -glucan content of up to 15%, have been consumed safely for over 10 years. This ingredient was developed in the late 1980s as a fat replacer and has been extensively used by different manufacturers. The use of this product has been approved in a variety of food products such as fresh ground meat and poultry, processed meats and poultry products, salad dressings, mayonnaise, baked goods, baking mixes, processed cheese, yogurt, ice cream and frozen desserts, snack foods, margarines, and spreads, icings, and frostings, frozen entrees, and confections.

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Figure 1. Manufacturing Process of Oat β-Glucan (B-CAN™)

B-CAN™ OAT β-GLUCAN
Manufacturing Flow Chart



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Table 1. Specifications for Garuda's Oat β-Glucan (B-CAN™)

PARAMETER	CHARACTERISTICS	ASSAY METHOD
PHYSICAL CHARACTERISTICS		
Appearance	Beige to light grey/brown powder	Visual
Particle size	95% < US 60 mesh	Sieve test
Moisture	< 7%	USP 921
β-(1-3, 1-4) Glucan	≥ 70%	AOAC 995.16
HEAVY METALS		
Lead	≤ 1.0 ppm	AOAC 985.35
Arsenic	≤ 0.5 ppm	AOAC 985.35
Cadmium	≤ 1.0 ppm	AOAC 985.35
Mercury	≤ 1.0 ppm	AOAC 985.35
MICROBIOLOGICAL ASSAYS		
Total aerobic plate count	≤ 10,000 cfu/g	FDA BAM
Coliform	≤ 100 MPN/g	FDA BAM
<i>E. coli</i>	Negative (cfu/g)	FDA BAM
<i>Salmonella</i>	Negative (cfu/25 g)	FDA BAM
<i>Staphylococcus aureus</i>	Negative (cfu/g)	FDA BAM
Yeast	≤ 100 cfu/g	FDA BAM
Mold	≤ 100 cfu/g	FDA BAM

Typical compositional and nutritional analyses of Garuda's oat β-glucan product primarily containing over 70% β-glucan (B-CAN™) are summarized in Table 2.

Table 2. Nutritional Analyses of B-CAN™

NUTRIENT	AMOUNT/100 G	NUTRIENT	AMOUNT/100 G
Calories (kcal)	181	Sugars (total) (g)	2.15
Protein (g)	2.39	Lactose	< 0.05
Ash (g)	4.12	Sucrose	1.19
Saturated fat (g)	0.08	Glucose	< 0.02
Polyunsaturated fat (g)	0.08	Maltose	< 0.02
Trans-fatty acids (g)	0.01	β-Carotene (IU)	< 60
Monounsaturated fat (g)	0.13	Retinol (IU)	< 44
Cholesterol (mg)	< 1.0	Vitamin A (IU)	< 44
Sodium (mg)	0.41	Vitamin C (mg)	< 0.44
Total carbohydrate (g)	88.2	Calcium (mg)	140
Total dietary fiber (g)	81.0	Iron (mg)	11.3
Moisture (g)	5.0	Calories from total fat (kcal)	2.70

Calories are calculated based on 9 calories per gram of fat, 4 calories per gram of protein, zero calories per gram of insoluble fiber, 2 calories per gram of soluble fiber and 4 calories per gram of other non-fiber carbohydrates.

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2. Intended Food Categories for Addition of B-CAN™ & Estimated Daily Intake

Garuda intends to use oat β -glucan at levels that yield 0.75 to 3.0 g of β -glucan per serving of the following food categories: bars; beverages; breads, whole grain and specialty; breakfast cereals; cookies, lite; crackers, reduced fat; gravy and sauces, lite; instant rice; macaroni products; muffins, reduced fat; salad dressings, lite; snack chips, reduced fat; soups; tomato-based sauces; tortillas and taco shells; vegetarian patties/crumbles; yogurt, and reduced fat.

In addition to these named food categories, B-CAN™ is intended for use under the supervision of a physician in medical foods at levels not to exceed 3.0 g β -glucan/person/day. Under Section 5(b) of the Orphan Drug Act (ODA), a medical food is defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and that is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. The intended use(s) of B-CAN™ in medical foods will reflect these and other applicable regulations. Foods that are intended for infants and toddlers, such as infant formulas or foods formulated for babies or toddlers, and meat and poultry products are excluded from the list of intended food uses of the subject oat β -glucan. Garuda recognizes that the use levels of oat fiber are self-limiting for technological reasons since excessive levels of oat fiber can adversely alter the flavor and/or texture of the food.

Except for exclusion from meat and poultry products, the intended food category uses of Garuda's oat β -glucan are the same and will be at identical levels of addition as described by Cargill Incorporated for its barley β -glucan as reported in GRN 344 (FDA 2011) and in GRN 207. Cargill provided its "all uses" estimate in GRN 344 that consisted of both the additional new intended use in meat-containing soups, sauces, and gravies and the revised estimate of exposure from the intended uses described in GRN 207. Cargill estimated that the combined average intake of barley fiber by consumers from all uses of barley fiber in both GRNs 207 and 344 would be 12.4 g/person/day (8.7 g β -glucan/person/day). The 90th percentile intake was estimated as 23.5 g/person/day (16.5 g β -glucan/person/day). Cargill reported that its barley fiber would be added at levels up to 4.3 g/serving, resulting in approximately 3 g of β -glucan/serving. Given the levels of β -glucan ($\geq 70\%$) in both Garuda's oat β -glucan product (B-CAN™) and Cargill's barley betafiber (Barliv™), the estimated intake of β -glucan from proposed uses of Garuda's product will be equivalent (i.e., 8.7 and 16.5 g β -glucan/person/day for the mean and 90th percentile, respectively). Since Garuda is not proposing to use B-CAN™ in meat and poultry products, the resulting estimated intake is likely to be less than these values. The intended uses of B-CAN™ that are similar to those uses described in GRN 344 and GRN 207 are unlikely to affect the dietary intake of β -glucan from introduction into the market by another supplier who will have to compete in essentially the same market and food categories. Hence, there is no need for a cumulative intake analysis.

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III. SCIENTIFIC EVIDENCE OF OAT β -GLUCAN & B-CAN™ SAFETY

A. Common Knowledge of Safe Use of Oats

There is a long history of human consumption of oats as a food. Oats as currently used originated in Asia as wild red oats. Oats have been cultivated in various parts of the world for over 2000 years. In many countries in Europe---such as Scotland, Germany, Great Britain, and the Scandinavian countries---cultivation of oats was widespread. In these countries, oats constituted an important commercial crop since they were a dietary staple for the people. In the early 17th century, oats were brought to North America by Scottish settlers. In recent years, the US, Germany, Russian, Canada, France, Finland, Poland, and Australia are the largest commercial producers of oats. Available per capita consumption data from USDA suggest that Canada ranks as the number one consumer of oat products followed by Australia and Russia. Based on the USDA National Nutrient Database (NDSR, 2009), 139 food products marketed in the US contain oats.

As reported in Encyclopedia Britannica (2012), in addition to its main use as livestock feed, oats are processed for human consumption, especially as breakfast foods. One of the commonly used oat-based foods, oatmeal, is prepared from rolled oats---flattened kernels with the hulls removed. β -Glucan is found in the cell walls of oat kernels. The traditionally recognized palatable "edible" portion of the whole oat contains certain tissues, e.g., strands of celluloses, hemicelluloses and pentosans (xylans in particular) that are unevenly distributed throughout the whole kernel, including the oat groat (dehulled oat). In recent years oat fiber has risen in its popularity as a highly desirable food ingredient in several finished food products, such as oat fiber-enriched bakery goods, ready-to-eat cereals, energy bars, and reduced and low calorie meal-replacement products.

The dietary intake guidelines do not distinguish between soluble or insoluble fiber. In the Dietary Guidelines for Americans, the US Department of Health and Human Services (HHS) and USDA (HHS/USDA, 2005) recommend that all adults eat half their grains as whole grains, which include oats and whole wheat. These guidelines also recommend that most Americans need to increase their intake of dietary fiber. In 2001, the Food and Nutrition Board of the Institute of Medicine established its first recommended intake levels for fiber (IOM, 2005). The adequate intake recommendation of total fiber for adults (\leq 50 years of age) is 38 g/day for men and 25 g/day for women. For adults (\geq 50 years of age), the recommendation is 30 g/day for men and 21 g/day for women. The daily reference value for dietary fiber is 25 g (for a 2000 calorie diet) [21 CFR 101.9(d)]. Dietary fiber intakes in the US average from 16-18 g/day for men and 12-14 g/day for women, which are well below recommended intake levels (IOM, 2005).

In addition to oat sources, β -glucan is commonly consumed from other cereals and edible plants such as barley, rye, wheat and mung beans. It is also found in yeast, mushroom and seaweed (Novak and Vetvicka, 2009). Available evidence from epidemiological studies and clinical trials has consistently revealed that fiber-rich diets are associated with significant reductions in cardiovascular disease risk. While there is no established dietary reference value (DRV) for soluble fiber, the amount of soluble fiber in a typical mixed diet is one-fourth to one-third of the total dietary fiber intake (ADA, 2002). The intended uses of B-CAN™ have the potential to increase the dietary fiber intakes among the US population, consistent with the HHS/USDA recommendations.

The available information demonstrates that there is broad-based common knowledge of the health benefits associated with the consumption of the fiber---particularly the fiber from oats. The available information further suggests that oats are commonly consumed from the diet, and there are no reported adverse effects from its consumption in food.

B. Regulatory Agency Reviews

1. FDA Qualified Health Claims

As described earlier, in 1997, FDA approved the health claim on the association of soluble fiber from rolled oats and reduced risk of heart disease (21 CFR 101.81) (62 FR 3584, January 23, 1997). In October 2002, in response to a petition jointly filed by the Quaker Oats Co. and Rhodia, Inc., FDA (2002) amended the 1997 health claim for soluble fiber from rolled oats to add an additional eligible source of whole oat β -glucan soluble fiber, the soluble fraction of α -amylase-hydrolyzed oat bran or whole oat flour with a β -glucan soluble fiber content at levels up to 10%. The agency concluded, based on the publicly available scientific evidence that---in addition to rolled oats, oat bran, and whole oat flour---the soluble fraction of α -amylase-hydrolyzed oat bran or whole oat flour with a β -glucan content up to 10% and not less than that of the starting material is an appropriate source of β -glucan soluble fiber for the health claim. Regarding safety, the petitioners determined their product to be GRAS, and the basis of the safety determination for their products (containing up to 25% β -glucan) was the similarity to other existing cereal adjuncts, such as pre-cooked flours, pre-cooked bran, and starches. Following its review, FDA concluded that the petitioners satisfied the preliminary requirement of 21 CFR 101.14(b)(3)(ii) to demonstrate to FDA's satisfaction that the use of oatrim, as described previously, is safe and lawful as a food ingredient at levels necessary to justify the health claim.

Along with the health claims for oat products, in December 2005, the FDA authorized a health claim for soluble fiber from whole grain barley and barley-containing products and coronary heart disease ("CHD") (21 CFR 101.81) (FDA, 2005). In August 2008, FDA published a final regulation authorizing barley betafiber as an eligible source of soluble fiber for this health claim (FDA, 2008a). To qualify for the health claim, the barley soluble fiber-containing foods must provide at least 0.75 g of β -glucan soluble fiber per serving of the food. In 2008, the agency published a final regulation on the health claim regulation entitled "Soluble fiber from certain foods and risk of coronary heart disease (CHD)" to add barley betafiber as an additional eligible source of β -glucan soluble fiber. In support of the safety of barley derived β -glucan ($\geq 70\%$), the petitioner asserted that its product is GRAS. FDA also received a GRAS notice, GRN 207 (FDA 2006) on this subject and issued a letter stating that the agency had "no questions" about the GRAS determination under the intended conditions of use.

2. EFSA Health Claim Review

Similar to FDA, the European Food Safety Authority (EFSA) has also authorized a health claim related to the maintenance of normal blood cholesterol concentrations for soluble cereal fibers, particularly β -glucan from oats (EFSA, 2010). In an opinion on the scientific substantiation of a health claim related to oat β -glucan and lowering of blood LDL and total cholesterol, the EFSA Panel concluded that a cause and effect relationship has been established between the consumption of oat β -glucan and lowering of blood LDL-cholesterol concentrations. In order to

bear the claim, the Panel recommended that foods should provide at least 3 g of oat β -glucan/day. In an earlier (and similar) health claim approval, EFSA (2009) also agreed to the following claim for β -glucan: maintenance of normal blood cholesterol concentrations and maintenance or achievement of a normal body weight.

The EFSA Panel also evaluated the safety of β -glucan derived from yeast for use as a novel food ingredient in a variety of foods and beverages (EFSA, 2011). The Panel noted that the intake scenario for yeast β -glucan is somewhat similar to the background intake of β -glucan from other dietary sources. The Panel noted that β -glucan from other sources has already been evaluated for safety by EFSA. The Panel concluded that, on the basis of the nature of yeast β -glucan---the significant history of use of its source (baker's yeast)---and the intake estimate provided, along with the supplementary data from human and animal studies, yeast β -glucan is safe at the proposed use conditions of up to 600 mg/day.

3. FDA Review of β -Glucan GRAS Notices

The FDA received two separate GRAS notifications on β -glucan derived from barley [GRN 344 (FDA, 2011) and GRN 207 (FDA, 2006)]. In these submissions, extensive data from the published literature on β -glucan were presented by the notifier. FDA did not question the acceptability and suitability of the available evidence to support the safe use of β -glucan suggesting that the agency is comfortable with the GRAS determination of β -glucan for its proposed use levels in selected foods as presented in these GRNs. In these notices extensive safety data on oat-derived β -glucan were used to support safety of barley β -glucan. Since the subject of the GRAS determination described in this notice is substantially equivalent to the products described in these cited FDA notifications, the studies described in the FDA GRAS notifications are directly applicable to support the safety-in-use determination in the present GRAS assessment of B-CAN™. As reported earlier, β -glucan derived from oats or barley contains polysaccharides of unbranched, linear, mixed-linkage (1-3), (1-4)- β -D-glucan, and from a physiological perspective there is virtually no difference. Thus, from a safety perspective, the available studies of barley β -glucan and the studies described in GRN 344 and GRN 207 are fully applicable to the safety assessment of oat β -glucan. No recent studies raising any new safety concerns have appeared in the published literature subsequent to these evaluations, particularly the most recent GRAS notice GRN 344.

In addition to barley β -glucan, FDA has also reviewed GRAS notices on other sources of β -glucan such as yeast [GRN 309 (FDA, 2010); GRN 239 (FDA, 2008b)], and FDA has issued “no questions” letters in response to these submissions. As indicated earlier, chemically there are some minor differences in the β -glucan derived from yeast to that from oats. However, the available information, particularly from a metabolic perspective, indicates that these molecules will be handled similarly in the body. The studies described in these GRAS notices further corroborate the safety-in-use of oat β -glucan.

C. Human Experience & Testing

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Over 150 clinical trials in human subjects have been reported in the published literature following oral administration of products containing β -glucan derived from oats, barley and other sources. The objective of the majority of these studies was to examine the effect of β -glucan intake on blood cholesterol and/or glucose levels. Although the primary end point of these investigations was to

study the efficacy, some studies included clinical observations reported as adverse events. These studies provide an indirect opportunity to access the safety and “tolerability” of β -glucan in a diverse population. Several of the clinical trials were double-blind placebo-controlled trials that are not considered to result in bias. These clinical trials are summarized in the recent FDA GRAS notices—particularly GRN 344 (FDA, 2011), the EFSA (2010) report, FDA Health Claim (FDA, 1997, 2002), and several meta-analysis studies (Ripsin et al., 1992; Brown et al., 1999; Whitehead et al., 2008; Tiwari and Cummins, 2011; and Othman et al., 2011). These summary reports of clinical trials did not indicate any significant safety concern following consumption of products containing β -glucan.

As indicated above and given the safe uses of oats and products derived from oats, there is a lack of specifically designed published safety studies of oat β -glucan concentrates. However, some of the products containing oat β -glucan have been tested *via* clinical trials in food matrices that included muffins, cereals, breads, and beverages (Beer et al., 1995; Behall et al., 1997, 1998; Braaten et al., 1994; Pick et al., 1996; Torronen et al., 1992; FDA, 2011; and Othman et al., 2011). In these trials (such as those described in GRN 344), foods containing oat β -glucan concentrates at β -glucan levels up to 80% were well accepted by clinical trial participants. In studies that reported adverse effects, only mild, transient gastrointestinal adverse effects, such as flatulence and abdominal discomfort, were reported (Beer et al., 1995; Behall et al., 1997, 1998). These effects were similar to the ones noted when individuals abruptly shift from a low fiber diet to a high fiber diet. No major adverse gastrointestinal disturbances, or choking, have been reported with the use of oat β -glucan concentrates (FDA, 2011). In addition to these trials, several other trials failed to reveal any significant adverse effects of dietary exposure to β -glucan derived from barley or oats (Hallfrisch et al., 2003; Biorklund et al., 2005; Alminger and Eklund-Jonsson, 2008; Liatis et al., 2009). Some of these recent trials are also described in GRN 344 (FDA, 2011). A search of updated published literature performed for safety related information subsequent to the search performed for the most recent GRN 344 (since March 2010 to March 2012), using the terms “oat β -glucan, safety and/or toxicity” did not reveal any safety or toxicity related publications that would alter previous safety assessments.

Several oat β -glucan concentrates, such as oatrim (with up to 10% β -glucan) and OatVantage™ (with 54% β -glucan), that are currently in the US marketplace have GRAS status (FDA, 2011). In 1992, Quaker Oats Co. determined that oatrim containing β -glucan (4-6%) is GRAS based on several independent factors. For their assessment, the following factors were considered:

- oatrim is similar to oat starch and maltodextrin—two food ingredients with acknowledged safety;
- the enzymatic manufacturing process of oatrim is analogous to the biological digestion of starch in humans; and
- a short-term toxicity study and safety evaluations of oatrim's constituents did not reveal any areas of concern (FDA, 2011).

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In the Quaker-Rhodia Petition (2001) to FDA, the safety of oat β -glucan was also evaluated and described. The petitioner claimed that there is a lack of evidence of any significant adverse effects related to oat fiber intake and gastrointestinal disturbances, choking, or vitamin-mineral mal-

absorption. Additionally, the estimations using nationally representative data on increased total and soluble dietary fiber intakes from greater oat β -glucan intakes with oatrim (BetaTrim™)-containing foods do not indicate that fiber intakes will rise to levels that would trigger safety concerns. To support this conclusion, several studies were reviewed and described in the Quaker-Rhodia Petition (2001).

It is well-recognized that certain dietary fibers can delay absorption of triacylglycerol, and there have been indications that fiber intake may alter absorption of fat-soluble vitamins. Regarding effects of consumption of specific fibers on absorption of fat soluble vitamins, only limited information is available. The available studies on the effect of fiber on fat-soluble vitamin and mineral absorption are inconsistent (Rattan et al., 1981; Wahal et al., 1986). Evidence from these and other studies do not suggest that increased fiber consumption in general is likely to significantly affect absorption of vitamins (Anderson et al., 1980). In addition to vitamins, the effects of various dietary fibers on mineral absorption have also been investigated in some studies, again, with inconsistent findings. The available evidence is not sufficient to draw conclusions concerning the effects of particular fiber types (including oat fibers) or fiber mixtures on mineral absorption. Gordon et al. (1995) reported that evidence to support effects of fiber on mineral absorption is lacking. Overall, there is no compelling evidence that consumption of fiber, including soluble fibers, adversely impairs the absorption of vitamins or essential minerals in adequately nourished populations.

It is well known that soluble fiber is resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine. Fermentation rates of dietary fiber widely vary, and soluble fiber such as β -glucan tends to be more readily fermented compared to cereal dietary fiber. Soluble fiber absorbs water and is fermented in the colon by bacteria which results in the formation of short-chain fatty acids, carbon dioxide, hydrogen and methane.

D. Animal Studies

In addition to human studies, in several animal experiments, effects of β -glucan derived from different sources including oats have been investigated. The majority of the literature reports pertaining to animal studies of β -glucan derived from oats and barley is summarized in FDA GRAS notices GRNs 207 and 344 (FDA, 2006, 2011), while studies related to yeast β -glucan safety are summarized in GRNs 239 and 309 (FDA, 2008b, 2010). Regarding the animal safety studies in particular, the most recent GRAS notice (GRN 344) has extensively described safety data pertaining to β -glucan derived from barley and oat. Also in these studies, no significant adverse effects tied to β -glucan ingestion were noted. A search of updated literature for oat β -glucan safety and/or toxicity did not reveal any publications citing safety concerns.

E. Adverse Effects of Dietary Fiber Reported by IOM

The IOM committee did not establish a tolerable upper intake level (UL) for dietary or functional fiber. As reported in the IOM (2005) report, dietary fibers—such as guar gum, inulin, polydextrose, oligofructose, fructooligosaccharides, resistant starch, and psyllium—may cause gastrointestinal distress that may include abdominal cramping, bloating, gas, and diarrhea. It is well recognized that a sudden increase in the intake of dietary fiber in some people may result in abdominal

cramping, bloating or increased production of gas. These symptoms can be minimized or avoided by increasing intake of fiber-rich foods gradually and increasing fluid intake to ~2 liters/day.

It has been reported that the addition of cereal fiber to meals may decrease the absorption of iron, zinc, calcium, and magnesium in the same meal. However, available evidence indicates that the phytate present in the cereal fiber rather than the fiber itself may be the agent responsible for the decreased mineral absorption. In general, dietary fiber as part of a balanced diet has not been found to adversely affect the calcium, magnesium, iron, or zinc status of healthy people at recommended intake levels (IOM, 2005).

F. Allergenicity

It has been reported that farmers with grain dust allergy and children with atopic dermatitis can exhibit allergic reactions to oat proteins. These proteins can act as both respiratory and skin allergens (Baldo et al., 1980; Pazzaglia et al., 2000; De Paz Arranz et al., 2002; Codreanu et al., 2006; Boussault et al. 2007). Allergy manifestation resulting from consumption of oats and oat products has been debated. It has been alleged that oats may cause adverse effects in individuals with celiac disease. As a result, use of oats in gluten-free diet was not allowed. Evidence from more recent reports indicates that oats are safe for consumption by most individuals with celiac disease (Rashid et al., 2007). Health Canada (2007) critically reviewed the scientific literature and concluded that the majority of people with celiac disease can tolerate moderate amounts of pure oats that are uncontaminated with other cereal grains such as wheat, barley and rye. It is recognized that commercially available oats are variably contaminated with gluten-containing grains that can occur on the farms, during the growing cycle or during storage, cleaning, transportation or processing. Garuda has periodically analyzed its B-CAN™ materials for the presence of gluten and to date none of the test results revealed the presence of gluten.

Garuda reports that B-CAN™ products do not contain any of the eight foods considered to be major food allergens---milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, soybeans, and wheat) under the 2004 US Food Allergen Labeling and Consumer Protection Act (FALCPA).

IV. EXPERT PANEL ASSESSMENT & DISCUSSION OF COMPOSITE SAFETY INFORMATION FOR B-CAN™ GRAS STATUS

A. FDA GRAS Criteria

FDA defines “safe” or “safety” as it applies to food ingredients as

“...reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of

scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance.”²

Amplification is provided in that the determination of safety is to include probable consumption of the substance in question, the cumulative effect of the substance, and appropriate safety factors. It is FDA’s operational definition of safety that serves as the framework against which this evaluation is provided.

Furthermore, in discussing GRAS criteria, FDA notes that

“...General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.”³

FDA discusses in more detail what is meant by the requirement of general knowledge and acceptance of pertinent information within the scientific community, i.e., the so-called “common knowledge element,” in terms of the two following component elements:⁴

- Data and information relied upon to establish safety must be generally available, and this is most commonly established by utilizing published, peer-reviewed scientific journals; and
- There must be a basis to conclude that there is consensus (but not unanimity) among qualified scientists about the safety of the substance for its intended use, and this is established by relying upon secondary scientific literature such as published review articles, textbooks, or compendia, or by obtaining opinions of expert panels or opinions from authoritative bodies, such as the National Academy of Sciences.

As noted below, this safety assessment to ascertain GRAS status for high purity β -glucan for the specified food uses meets FDA criteria for reasonable certainty of no harm by considering both the technical and common knowledge elements. Both the scientific elements and the common knowledge elements that FDA has identified as essential components of valid GRAS determinations have been met.

B. Panel Findings on Safety of β -Glucan

Garuda’s oat β -glucan preparations---B-CAN™---containing $\geq 70\%$ β -glucan has been fully characterized and meets the food grade specifications appearing in Table 1. It is manufactured from food grade oats in accordance with current Good Manufacturing Practices requirements.

Oats are viewed as a traditional food that have been commonly and safely consumed for centuries and is a mainstay of US diets while being consumed in substantial quantities on an international

² See 21 CFR 170.3(i).

³ See 21 CFR 170.30(a).

⁴ See *Federal Register* 62 April 17, 1997, 18937; as cited in footnote 1.

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scale. The cumulative information did not reveal any adverse effects as a consequence of consumption of oats and oat products as foods.

The primary component ($\geq 70\%$) of oat fiber, (1-3)- and (1-4)- β -glucan, is also widely found in common dietary grains and other plants. Thus, β -glucan is not only consumed from oats but also from other cereals such as barley, rye, wheat, and mung beans and selected other edible plants. Consumption of such foods containing β -glucan has not been reported to result in any adverse effects. Along with its consumption over the course of centuries as a constituent of oats, oat-derived β -glucan products have been safely consumed over the past decade.

In several human and animal studies, β -glucan from different sources---such as oats, barley, yeast and mushrooms---has been extensively investigated. A majority of these studies have been published in peer-reviewed journals. The Panel has reviewed the data on oat β -glucan as well as the data on other similar soluble fibers.

The available information suggests that as a dietary fiber, β -glucan is unlikely to be absorbed from the gastrointestinal track to any significant extent due to its large molecular size. Hence any systemic effects of β -glucan are unlikely.

Similar to any other fiber, β -glucan is fermented in the colon by bacteria which results in the formation of short-chain fatty acids, along with carbon dioxide, hydrogen and methane. It has been suggested that solubility of fiber does not reliably predict the physiological effects of fiber (EFSA, 2009).

In the recent GRAS notice on β -glucan (GRN 344) derived from barley, the notifier extensively reviewed and evaluated the safety related human and animal studies on β -glucan, including that derived from oats. No adverse effects of β -glucan were noted. In GRN 344 as well as in an earlier GRAS notice (GRN 207) on the same subject, the notifier relied in part on the safety data for oat β -glucan to support the GRAS determination of barley β -glucan. In each of these cases FDA concurred with the safety conclusions of the designated food uses for β -glucan.

The available evidence related to adverse effects reveals that---apart from some mild and short-lived gastrointestinal side effects, such as flatulence and abdominal discomfort---no major gastrointestinal or esophageal obstructions have been reported following β -glucan ingestion. Gastrointestinal side effects have usually been noted in individuals who abruptly switched to a high fiber intake from a low fiber diet. A gradual increase in dietary fiber intake is unlikely to result in adverse effects.

There is no adequate evidence to support the position that dietary exposure to fiber, including soluble fibers, adversely affects the absorption of vitamins or essential minerals.

The Panel is of the opinion that there is no need for any classical absorption, disposition, metabolism and excretion studies as β -glucan, the main component of B-CAN™, is not digested by human digestive enzymes and its molecular size precludes absorption to any significant amounts while passing through the gastrointestinal tract.

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C. Common Knowledge Elements for GRAS Determination

The first common knowledge element for a GRAS determination requires that data and information relied upon to establish general recognition of safety must be generally available; this is most commonly established by utilizing published, peer-reviewed scientific journals. The majority of studies summarized as part of this safety assessment have been published in the scientific literature as reported in Section III.

Specifically, studies by Beer et al. (1995) and Behall et al. (1997, 1998) investigated the adverse effects of oat β -glucan. Furthermore, in several published animal studies described in GRN 344, the safety of oat β -glucan has been evaluated. In addition to the many scientific studies that have been conducted and published, history of consumption of oat products on a global scale since ancient times is well known. Also see Section III.A for additional discussion of selected common knowledge considerations.

The determination that B-CAN™ meets the applicable requirements for the technical element and common knowledge element for GRAS status is the result of a consensus among a panel of qualified experts that there was reasonable certainty that this notified substance, B-CAN™, containing $\geq 70\%$ β -glucan, would not be harmful under the intended conditions of use. The scientific data and information summarized in this GRAS notification reflect a review of the relevant literature dealing with the ingestion of oat β -glucan. The information on oat β -glucan and products containing β -glucan derived from other sources is extensive and can be found in numerous sources, compendia, books, and reviews. Furthermore, safety information for food uses of β -glucan has been favorably reviewed by EFSA (2010; 2011), and compelling safety documentation is found in several GRAS notices (GRN 344, GRN 309, GRN 239; and GRN 207). Information contained in GRAS notifications that have been submitted to FDA is generally available for review and evaluation by the scientific community. The composite information noted thereby fulfills the common knowledge element required for GRAS determinations.

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V. CONCLUSIONS⁵

The cumulative scientific information on oat β -glucan in general and on B-CAN™ in particular when specifically considering the human experiences and associated testing, anticipated human consumption levels, and germane supporting information, provides the basis for the conclusion that a daily oat β -glucan exposure that provides 8.7 g β -glucan as the mean adult per capita consumption level and 16.5 g β -glucan for the 90th percentile adult consumer, with proposed food usage as summarized in Section II.F.2 of this document, is generally recognized as safe. B-CAN™ must be produced in accordance with GMP procedures and must comply with appropriate food grade specifications as noted in Table 1.

We have independently and collectively evaluated the above-referenced information and offer this GRAS declaration based on scientific procedures in accordance with FDA's standard for food ingredient safety, i.e., reasonable certainty of no harm under the intended conditions of use.

Adult human exposure to Garuda's oat β -glucan—also referred to as B-CAN™—as an ingredient added to selected food categories at a combined level that provides up to 16.5 g/day of β -glucan derived from oats is generally recognized as safe (GRAS).

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Robert S. McQuate, Ph.D.

(b) (6)

Madhusudan G. Soni, Ph.D., FACN, FATS

July 19, 2012

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⁵ The Expert Panel members have extensive technical backgrounds in the evaluation of food ingredient safety. Dr. McQuate worked on GRAS and food additive safety issues within FDA's food additive and GRAS evaluation offices earlier in his career and subsequently continued working within this area in the private sector. Pertinent background information can be found at www.gras-associates.com. Dr. Soni has worked within the private sector on food ingredient safety matters and has served on numerous GRAS Expert Panels. His curriculum vitae can be accessed at: <http://www.soniassociates.net>.

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APPENDIX

Analytical Results from Five Non-Consecutive Production Lots Of Garuda's B-CAN™

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Commodity: **B-CAN™** Oat Beta-Glucan, 70%
 Product Code: OGLUCAN70
 Lot Number: XXXXXXXXXX
 Test Date: July 12, 2011
 Manufacture Date: July 11, 2011
 Best used before: July 10, 2013
 Botanical Source: *Avena sativa*
 Country of Origin: China

<u>ITEM</u>	<u>Standard Limits</u>	<u>Results</u>	<u>Analytical Method</u>
<u>NUTRITIONAL</u>			
Moisture:	< 7.0 %	3.6 %	USP<921>
<u>PHYSICAL</u>			
Appearance:	Beige to light grey/brown Powder	Complies	Visual
Particle Size:	95 % < U.S. 60 Mesh	98.5 %	Sieve Test
GMO Status:	Non-GMO	Non-GMO	Certification Only
<u>CHEMICAL</u>			
β 1,3 1,4 Glucan Content:	≥ 70 %	70.5 %	AOAC 995.16
Lead (Pb):	≤1.0 ppm	< 1.0 ppm	AOAC 985.35
Arsenic (as As ₂ O ₃):	≤0.5 ppm	< 0.5 ppm	AOAC 985.35
Cadmium (Cd):	≤1.0 ppm	< 1.0 ppm	AOAC 985.35
Mercury (Hg):	≤1.0 ppm	< 1.0 ppm	AOAC 985.35
<u>MICROBIOLOGICAL</u>			
Total Aerobic Plate Count:	<10,000 CFU / g	< 680 CFU / g	FDA BAM
Coliform:	< 100 MPN / g	< 30 MPN / g	FDA BAM
<i>E. coli</i> :	Negative / g	Negative / g	FDA BAM
<i>Salmonella</i> :	Negative / 25g	Negative / 25g	FDA BAM
<i>Staphylococcus aureus</i> :	Negative / g	Negative / g	FDA BAM
Yeast:	≤ 100 CFU / g	< 10 CFU / g	FDA BAM
Mold:	≤ 100 CFU / g	< 10 CFU / g	FDA BAM

GARUDA INTERNATIONAL, INC.

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Quality Assurance

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Commodity: B-CAN™ Oat Beta-Glucan, 70%
Product Code: OGLUCAN70
Lot Number: [REDACTED]
Test Date: August 23, 2011
Manufacture Date: August 08, 2011
Best used before: August 07, 2013
Botanical Source: Avena sativa
Country of Origin: China

<u>ITEM</u>	<u>Standard Limits</u>	<u>Results</u>	<u>Analytical Method</u>
<u>NUTRITIONAL</u>			
Moisture:	< 7.0 %	6.15 %	USP<921>
<u>PHYSICAL</u>			
Appearance:	Beige to light grey/brown Powder	Complies	Visual
Particle Size:	95 % < U.S. 60 Mesh	98.5 %	Sieve Test
GMO Status:	Non-GMO	Non-GMO	Certification Only
<u>CHEMICAL</u>			
β 1,3,1,4 Glucan Content:	≥ 70 %	70.7 %	AOAC 995.16
Lead (Pb):	≤1.0 ppm	0.026 ppm	AOAC 985.35
Arsenic (as As ₂ O ₃):	≤0.5 ppm	< 0.027 ppm	AOAC 985.35
Cadmium (Cd):	≤1.0 ppm	< 0.007 ppm	AOAC 985.35
Mercury (Hg):	≤1.0 ppm	< 0.011 ppm	AOAC 985.35
<u>MICROBIOLOGICAL</u>			
Total Aerobic Plate Count:	<10,000 CFU / g	< 710 CFU / g	FDA BAM
Coliform:	< 100 MPN / g	< 6 MPN / g	FDA BAM
E. coli:	Negative / g	Negative / g	FDA BAM
Salmonella:	Negative / 25g	Negative / 25g	FDA BAM
Staphylococcus aureus:	Negative / g	Negative / g	FDA BAM
Yeast:	≤ 100 CFU / g	< 20 CFU / g	FDA BAM
Mold:	≤ 100 CFU / g	< 20 CFU / g	FDA BAM

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Quality Assurance

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000029



**Certificate
Of Analysis**



Commodity: **B-CAN™** Oat Beta-Glucan, 70%
 Product Code: OGLUCAN70
 Lot Number: XXXXXXXXXX
 Test Date: August 23, 2011
 Manufacture Date: August 16, 2011
 Best used before: August 15, 2013
 Botanical Source: *Avena sativa*
 Country of Origin: China

<u>ITEM</u>	<u>Standard Limits</u>	<u>Results</u>	<u>Analytical Method</u>
<u>NUTRITIONAL</u>			
Moisture:	<7.0 %	6.08 %	USP<921>
<u>PHYSICAL</u>			
Appearance:	Beige to light grey/brown Powder	Complies	Visual
Particle Size:	95 % < U.S. 60 Mesh	98.4 %	Sieve Test
GMO Status:	Non-GMO	Non-GMO	Certification Only
<u>CHEMICAL</u>			
β 1,3 1,4 Glucan Content:	≥ 70 %	71.4 %	AOAC 985.16
Lead (Pb):	≤1.0 ppm	0.019 ppm	AOAC 985.35
Arsenic (as As ₂ O ₃):	≤0.5 ppm	<0.034 ppm	AOAC 985.35
Cadmium (Cd):	≤1.0 ppm	<0.009 ppm	AOAC 985.35
Mercury (Hg):	≤1.0 ppm	<0.014 ppm	AOAC 985.35
<u>MICROBIOLOGICAL</u>			
Total Aerobic Plate Count:	<10,000 CFU / g	<790 CFU / g	FDA BAM
Coliform:	< 100 MPN / g	< 6 MPN / g	FDA BAM
<i>E. coli</i> :	Negative / g	Negative / g	FDA BAM
<i>Salmonella</i> :	Negative / 25g	Negative / 25g	FDA BAM
<i>Staphylococcus aureus</i> :	Negative / g	Negative / g	FDA BAM
Yeast:	≤ 100 CFU / g	< 20 CFU / g	FDA BAM
Mold:	≤ 100 CFU / g	< 20 CFU / g	FDA BAM

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Commodity: **B-CAN™** Oat Beta-Glucan, 70%
 Product Code: OGLUCAN70
 Lot Number: XXXXXXXXXX
 Test Date: September 16, 2011
 Manufacture Date: September 15, 2011
 Best used before: September 14, 2013
 Botanical Source: *Avena sativa*
 Country of Origin: China

<u>ITEM</u>	<u>Standard Limits</u>	<u>Results</u>	<u>Analytical Method</u>
<u>NUTRITIONAL</u>			
Moisture:	< 7.0 %	4.5 %	USP<921>
<u>PHYSICAL</u>			
Appearance:	Beige to light grey/brown Powder	Complies	Visual
Particle Size:	95 % < U.S. 60 Mesh	98.5 %	Sieve Test
GMO Status:	Non-GMO	Non-GMO	Certification Only
<u>CHEMICAL</u>			
β 1,3 1,4 Glucan Content:	≥ 70 %	70.2 %	AOAC 995.16
Lead (Pb):	≤1.0 ppm	< 1.0 ppm	AOAC 985.35
Arsenic (as As ₂ O ₃):	≤0.5 ppm	< 0.5 ppm	AOAC 985.35
Cadmium (Cd):	≤1.0 ppm	< 1.0 ppm	AOAC 985.35
Mercury (Hg):	≤1.0 ppm	< 1.0 ppm	AOAC 985.35
<u>MICROBIOLOGICAL</u>			
Total Aerobic Plate Count:	<10,000 CFU / g	< 840 CFU / g	FDA BAM
Coliform:	< 100 MPN / g	< 6 MPN / g	FDA BAM
<i>E. coli</i> :	Negative / g	Negative / g	FDA BAM
<i>Salmonella</i> :	Negative / 25g	Negative / 25g	FDA BAM
<i>Staphylococcus aureus</i> :	Negative / g	Negative / g	FDA BAM
Yeast:	≤ 100 CFU / g	< 20 CFU / g	FDA BAM
Mold:	≤ 100 CFU / g	< 20 CFU / g	FDA BAM

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000031



Commodity: B-CAN™ Oat Beta-Glucan, 70%
Product Code: OGLUCAN70
Lot Number: [REDACTED]
Test Date: December 19, 2011
Manufacture Date: November 04, 2011
Best used before: November 03, 2013
Botanical Source: *Avena sativa*
Country of Origin: China

<u>ITEM</u>	<u>Standard Limits</u>	<u>Results</u>	<u>Analytical Method</u>
<u>NUTRITIONAL</u>			
Moisture:	< 7.0 %	4.88 %	USP<921>
<u>PHYSICAL</u>			
Appearance:	Beige to light grey/brown Powder	Complies	Visual
Particle Size:	95 % < U.S. 60 Mesh	98.0 %	Sieve Test
GMO Status:	Non-GMO	Non-GMO	Certification Only
<u>CHEMICAL</u>			
β 1,3 1,4 Glucan Content:	≥ 70 %	70.2 %	AOAC 995.16
Lead (Pb):	≤1.0 ppm	0.019 ppm	AOAC 985.35
Arsenic (as As ₂ O ₃):	≤0.5 ppm	0.042 ppm	AOAC 985.35
Cadmium (Cd):	≤1.0 ppm	< 0.008 ppm	AOAC 985.35
Mercury (Hg):	≤1.0 ppm	< 0.012 ppm	AOAC 985.35
<u>MICROBIOLOGICAL</u>			
Total Aerobic Plate Count:	<10,000 CFU / g	< 1,200 CFU / g	FDA BAM
Coliform:	< 100 MPN / g	< 6 MPN / g	FDA BAM
<i>E. coli</i> :	Negative / g	Negative / g	FDA BAM
<i>Salmonella</i> :	Negative / 25g	Negative / 25g	FDA BAM
<i>Staphylococcus aureus</i> :	Negative / g	Negative / g	FDA BAM
Yeast:	≤ 100 CFU / g	< 20 CFU / g	FDA BAM
Mold:	≤ 100 CFU / g	< 20 CFU / g	FDA BAM

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SUBMISSION END

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