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February 6, 2012

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Division of Biotechnology and GRAS Notice Review

Antonia Mattia, Ph.D.
Office of Food Additive Safety
Division of Biotechnology and GRAS Notice Review (HFS-255)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: GRAS Notification for RIBUS, Inc. Ground rice hull

Dear Dr. Mattia,

This is to notify you that RIBUS, Inc., claims that the use of the substance described below (ground rice hull) is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because RIBUS, Inc. has determined such use to be Generally Recognized As Safe (GRAS).

RIBUS, Inc. assembled a panel of experts highly qualified by scientific training and experience to evaluate the safety of the intended uses of ground rice hull. The panel included Dr. Robert Nicolosi, Dr. Joseph Borzelleca, and Dr. Michael Pariza. Following independent critical evaluation of the available data and information, the panel has determined that the use of ground rice hull (that is manufactured by RIBUS, Inc.) described in the enclosed notification in GRAS based on scientific procedures.

After reviewing the available data, the Expert Panel also concluded in its February 2012 statement that RIBUS's ground rice hull can be safely used as a food ingredient. This determination and notification are in compliance with proposed Sec. 170.36 of Part 21 of the Code of Federal Regulations (21 CFR section 170.36) as published in the Federal Register, Vol. 62, No. 74, FR 18937. April 17, 1997.

Notifier's name and address: RIBUS, Inc.
Attention: Neal Hammond (email address: neal@ribus.com)
Address: 8000 Maryland, Suite 460, St. Louis, MO 63105
Phone number: 916-969-9500

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Name of GRAS substance: Ground rice hull (Common or trade name: Nu-FLOW and Nu-FLAC)

Product description

RIBUS's ground rice hull is processed from whole rice hulls by a proprietary thermal process. Ground rice hull consists of mostly insoluble dietary fiber added to food for several purposes. Ground rice hull has >40% TDF (of which >90% is insoluble dietary fiber) and a particle size of <300 microns. The rice fiber contains no sulfites, added flavors, components from an animal source, BHA, BHT, genetically altered plant material, or irradiated material.

Specifications:

Specifications of ground rice hull

Macronutrient	% Unit	Analytical method
TDF (dry wt. basis)(a)	>40 %	AOAC 991.43
Protein	<7 %	AOAC 984.13
Starch	<2 %	AOAC 996.11
Fat	<1.5 %	AOAC 954.02
Moisture	<10.0 %	AOAC 934.01
Ash	<22 %	AOAC 900.02
pH, 5% slurry	7.3±0.5 pH	
Microbiological Specifications		
Total plate count	<10,000 cfu/g(b)	FDA-BAM2(c) Chap. 3
S. aureus	Negative cfu/g	FDA-BAM2 Chap. 4
E. coli	Negative cfu/g	FDA-BAM2 Chap. 4
Salmonella	Negative cfu/g	FDA-BAM2 Chap. 5
Yeast and mold	<200 cfu/g	FDA-BAM2 Chap.19

(a) TDF=total dietary fiber;
(b) cfu = colony forming units.
(c) BAM = Bacteriological Analytical Manual, January, 2001.

Applicable conditions of use of the notified substance

Ground rice hull is proposed for general food use at concentrations consistent with cGMP. Examples of food applications include, but are not limited to, prepared foods, nutraceuticals, functional foods, general foods (such as snack foods, bakery products, cereals, crackers, pasta products, dough conditioners, beverages, sports beverages), meal replacement, gluten-free foods, and medical foods. There will be a self-limiting effect of the use of ground rice hull in food for organoleptic limitations and technological reasons. In most cases, concentration of ground rice hull approaches technically feasible maximums (approximately 2-3% in beverages and some bakery products and 25% while being acceptable from a sensory perspective.

Probable consumption of ground rice hull

The Institute of Medicine (IOM), the National Academy of Sciences (NAS), has recommended a daily intake of 14 g fiber per 1,000 calories for Americans. Despite the recommendations of the IOM, most Americans consume inadequate amounts of dietary fiber. The median intakes of fiber in the U.S. were estimated to be approximately one half (42 to 62%) of the recommended levels, the Daily Reference Intakes (DRI). Over 90% of the U.S. population did not meet the daily recommended intake of fiber. Thus, both IOM and the USDA (Dietary Guidelines for

Americans) recommend increased consumption of dietary fiber for Americans. Currently, more than 30 types of fiber ingredients are available for food formulations. Despite the availability of various fiber ingredients, fiber intake by Americans has been steadily low over the past several years. Average (aged 6 mo to 74 yr) daily fiber consumption was 13.3 g in 1976-1980 (NHANES II) and 14.8 g in 2003-2006 (2003-2006 NHANES). Considering the differences in both dietary survey methodology and fiber analytical methods between the 1970's and 2000's, it is reasonable to conclude that fiber intake status did not change significantly over the past two or three decades.

Application of conventional fiber ingredients (e.g., wheat bran, rice bran, and corn bran) to food and beverage formulations has been limited due to their gritty mouth feel and insoluble nature. Compared to conventional rice bran, ground rice hull has improved mouth feel and functionality such as water holding capacity. Ground rice hull is expected to be used as a replacement for conventional fiber ingredients. Thus, it is not likely that the availability of a new ground rice hull ingredient will significantly boost fiber intake levels in the American population.

Basis of GRAS determination :

Review of the scientific literature, and through scientific procedures.

Review and copying statement

The data and information that serve as the basis for this GRAS determination will be sent to the FDA upon request, or are available for the FDA's review and copying at reasonable times at the office of RIBUS, Inc.

We enclose an original and two copies as well as a word file of this notification for your review.

If you have any questions, please contact me.

Sincerely,

Sincerely yours,

(b) (6)

Neal Hammond

Technical Director

Enclosures

JOSEPH F. BORZELLECA

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Report of the Expert Panel on the Generally Recognized as Safe (GRAS) Status of the Proposed Uses of Ground Rice Hulls

RIBUS convened a panel of internationally recognized experts ("Expert Panel"), qualified by their scientific training and experience to evaluate the safety of food and food ingredients, to critically evaluate the available information on ground rice hulls and determine the Generally Recognized as Safe (GRAS) status of the proposed uses of RIBUS' ground rice hulls in food and beverages. The Expert Panel, individually and then collectively, critically evaluated the materials summarized in the GRAS Notification prepared by RIBUS and other materials deemed appropriate including method of manufacture and product specifications, batch analyses, intended conditions of use, estimated exposure from the proposed uses and a critical assessment of the scientific literature on the safety of ground rice hulls and other dietary fibers.

Following its independent critical evaluation of this information, the Expert Panel convened by telephone and unanimously concluded that the proposed uses of RIBUS' ground rice hulls, manufactured consistent with current Good Manufacturing Practice (cGMP) and meeting the food grade specifications presented in the GRASN, are safe and GRAS based on scientific procedures and through experience based on common use in foods in accordance with section 201 (s) (21 U. S. C. §321 (s)) of the Federal Food, Drug, and Cosmetic Act (21U. S. C. §301 et. seq.) set forth at 21 CFR 170. 30.

It is the opinion of the Expert Panel that other qualified experts would concur with this conclusion.

(b) (6) [redacted] 24 Feb, 2012

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(b) (6) [redacted] 22 Feb 2012

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16 Feb 2012

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1. Introduction

Name and Address of Notifier
RIBUS, Inc.
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St. Louis, MO 63105

Rice is unique among the world's major crops because of its many uses and its capability to adapt to climatic, agricultural, and cultural conditions. Its ability to grow and produce high caloric food per unit area on all types of land makes rice the world's most important cereal crop. The importance of rice as the number one staple in the developing countries will grow as the human population increases at a higher rate than the developed world. Rice and rice products are the chief source of energy for 40% of the world's people.

2. Common or Usual Name of Substance

Ground rice hull also called Ground rice husk

Codex alimentarius

CM 1207 –	Rice hull
Class:	Process foods of plant origin
Type:	Secondary Food Commodities of Plant Origin
Category:	Milled Cereal Products (Early Milling Stages)

3. Raw materials

Rice hull (also called rice husk) consists of the outer shell covering the rice kernel. Rice hull is a by-product produced during the process of milling. The bran constitutes nearly 15% of the total grain (paddy), while the hull represents 20% of the paddy.

When harvested from the field, rice is in the form of paddy or rough rice, where the kernel is enveloped by a rice hull. After being dried, rice is first milled to remove the hull, yielding brown rice

4. Product Characteristics and Specifications

The ingredient that is the subject of this GRAS notification is a processed rice hull.

The origin of the Ground rice hull is 100% Oryza Sativa, nothing added or removed.

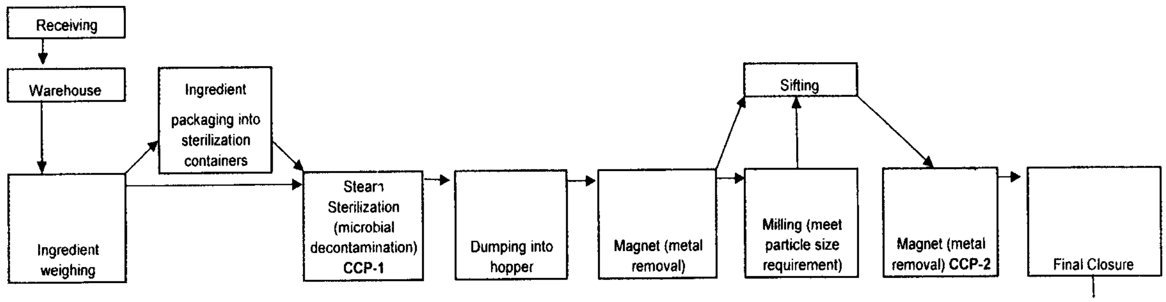
Physicochemistry and structure of ground rice hull
Ground rice hull has >40% TDF (of which >90% is insoluble dietary fiber) and a particle size of <300 microns. The Ground rice hull contains no sulfites, added flavors, components from an animal source, BHA, BHT, genetically altered plant material, or irradiated material.

Color:	Cream to beige
Flavor:	Bland to slightly sweet, no off flavors
Physical form:	Fine to coarse powder
Odor:	Natural clean cereal, no off odors
Particle size distribution:	<300 microns
Color:	Cream
Flavor:	Cereal

Particle Size: The material is ground to meet the desired particle size for functionality and size matching.
While typically light tan in color and odorless, it is all-natural and is subject to seasonal and slight variety variations in color, taste and odor.

5. Manufacturing Process
Because Ground rice hull makes up the outer protective coating of the rice kernel, it, like many seed coatings, arrives at the rice mill with a high microbiological load. The mill removes stones, and other extraneous materials. The hulls are heat sterilized to reduce the number of viable microorganisms. They are then ground to a particle size depending on the end use, and sifted to preserve a consistent size distribution. The Ground rice hull then passes through Rare Earth Magnets to remove any possible metal contamination, and is packaged.
Rice hull is tested annually for pesticide multiple residue analysis (MRA not to exceed Food Chemical Codex's maximum levels for human consumption), mycotoxin (not to exceed USDA's and FDA's maximum threshold), and heavy metals (not to exceed Food Chemical Codex's maximum levels for arsenic, cadmium, mercury, chromium, and lead).
Quality Control of Manufacturing Process
RIBUS, Inc. contracts with manufacturers to grind rice hulls with its inspected HACCP-designed manufacturing process. As well as the HACCP-designed manufacturing process, the contract manufacturers employ a plant sanitation program, pest control program, chemical control program (to ensure that chemical use in the plant for pest control, sanitation, maintenance, and laboratory use meets OSHA regulations), allergen control program (to identify, segregate, and control allergens), preventative maintenance program (to routinely maintain equipment), product recall program, customer complaint program.
Below is a flow-diagram of the HACCP plan for manufacturing the ground rice hull.

HACCP FLOW DIAGRAM



Physical/Chemical Specifications (Range)

Protein		1-7%
Fat		0- 1. 75%
Moisture		4%-10%
Carbohydrate		60%-76%
Total Dietary Fiber		40%-70%
Ash		16%-22%
Silica		15%-21% (95% of the Ash)
Iron		<0. 02%

Nutritional Composition

		Normal	**Low Moisture**
All per 100 g			
Calories		16	16
Protein		2. 8g	3g
Carbohydrates		68.7g	73.3g
	Digestible Carbohydrates	0. 2	0.2
	Dietary Fiber	68.5g	73.1g
Sugar		0. 2g	0.2g
	Glucose	<0. 2g	<0.2g
	Fructose	<0. 2g	<0.2g
	Sucrose	0. 2g	0.2g
	Maltose	<0. 2g	<0.2g
	Lactose	<0. 2g	<0.2g
Fat-Total		0. 4g	0.4g
	Saturated Fat	0. 2g	0.2g
	Monounsat Fat	0. 1g	0.1g
	Polyunsat Fat	0. 1g	0.1g
	Trans Fatty Acids	0	0
	Cholesterol	0	0
Ash		18. 1g	19.3g
Water		10g	4g

Microbiological Analysis

Microbiological Specifications		
Total plate count	<10,000 cfu/g(b)	FDA-BAM2(c) Chap. 3
S. aureus	Negative cfu/g	FDA-BAM2 Chap. 4
E. coli	Negative cfu/g	FDA-BAM2 Chap. 4
Salmonella	Negative cfu/g	FDA-BAM2 Chap. 5
Yeast and mold	<200 cfu/g	FDA-BAM2 Chap.19

Quality Control of the Manufacturing Process
RIBUS contracts with food manufacturers using a process similar to that used for other grains. In order to control the manufacturing process, RIBUS operates a self-audited HACCP program along with several other programs in order to manufacture high quality and pure product. RIBUS, Inc. manufactures the ground rice hull with its inspected HACCP-designed manufacturing process.
RIBUS' manufacturing system is audited by third parties on a regular basis. In addition, RIBUS' Ground rice hull is Oregon Tilth Certified Organic. The ground rice hull is also certified as Kosher by the Orthodox Union (OU), Pareve Status.

Quality Control of the Finished Product
RIBUS, Inc. tests its final product and issues corresponding certificates of analysis to ensure quality and adherence to the product specifications.

6. Proposed Conditions of Use
The product ground rice hull is intended for the addition to food as an anti-caking agent, flow aid and application for natural and organic processing (replacing silicon dioxide).
Silicon dioxide is approved for foods not to exceed 2% of the weight of the food.
Ground rice hull contains around 20% of naturally occurring silica similar to synthetic silicon dioxide. Ground rice hull will be used at levels consistent with Good Manufacturing Practices (cGMP). Examples of food applications include, but are not limited to: prepared foods, nutraceuticals, functional foods, general foods (such as snack foods, bakery products, cereals, crackers, pasta products, dough conditioners, and beverages), meal replacement, gluten-free foods, and medical foods. There will be a self-limiting effect of the use of ground rice hull in food for organoleptic limitations and technological reasons. Ground rice hull approach technically feasible maximums (approximately 5% in dry mix applications, and 35% as an adsorbent in liquids.

- **Examples of Applications of ground rice hull in Processed Foods** Ground rice hull can be specially formulated and optimized to meet needs and particle sizes. Anti-Caking Agent
- Adsorbent
- Carrier
- Chillproofing agent
- Filter aid
- Emulsifying agent
- Viscosity control agent
- Flow Aid
- Diluent
- Excipient
- Spice Blends
- Spray Drying
- Dry Blending
- Tableting
- Functions:
- Anti-Caking / Flow Aid
- Diluent
- Excipient
- Benefits:

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- Improve processing flows
- Achieve 95% organic level or higher
- Clean label (replace a synthetic)

RIBUS, Inc. estimates that its ground rice hull product will replace Silicon Dioxide as a free-flow agent in Organic products, and that it will reduce the amount of Silicon Dioxide used throughout the food industry.

Table 1 References to the use of rice hulls in food

Reference	**Table : Food Uses of rice hull**
Karavaj 2008	Rice husk products can be recommended for people suffering from overweight and in healthful and dietary meals
Augustine 1994	Expanded soft rusk--a new technique for the use of rice husk
Garelli 1928	Fat from rice hull
Sakai 1953	Beer like beverage in Japan
Bonardi 1970	Phytin and Inositol
Harding 1928	Fiber source for breakfast food, bread, muffins, etc
Rashidi	Study of Rice Bran application in production of Biscuit with high nutrition value
Vegas	Processing of rice husk autohydrolysis liquors for obtaining food ingredients
Moure 2006	Advances in the manufacture, purification and applications of xylo-oligosaccharides as food additives and nutraceuticals
Mussatto a 2007	Non-digestible oligosaccharides: A review

The regulation for Silicon Dioxide places a maximum use rate of 2% as a free-flow agent in foods. In supplements and tablets where the serving size is small, the dosage of ground rice hull will be small. Where it is used as a free-flow agent, the use rate will be larger. Where it is used as a carrier for liquids, the use rate will be the largest. RIBUS, Inc. estimates that ground rice hull will be consumed at a rate of between 20 mg and 200 mg per 10 gram serving.

7. Safety evaluation of rice hulls7.1. Long History of Safe Use

Rice is the oldest and most consumed grain in the world, feeding billions. The exact date and place of origin is not really known but one of the oldest mentions goes back almost 7000 years ago. Early people prepared rice for consumption by boiling the whole paddy rice in water, and consuming both the kernel and the outer hull. It was soon discovered that the hull could be separated from the kernel, exposing the edible portion of the rice using a large mortar, and pounding with a corresponding pestle.

Once the hull was removed, the rice consumer fed it to his animals as a source of roughage. Many studies have investigated the feed value of rice hulls in many types of animals. It is estimated that 80% of the concentrate fed to cattle in India consists of rice hulls. Govindarao 1980

7.2. Nutritional and Safety Studies of Rice Hulls

Absorption, Distribution, Metabolism and Excretion

Ground rice hulls, like most beta-linked fibers, are not digested by human pancreatic or brush border enzymes and are not expected to be absorbed intact. Rice hull enhances the viscosity of the gastrointestinal contents (Dikeman et al., 2006) which attenuates blood glucose and lipid concentrations. Once ground rice hulls reach the large intestine, they are fermented by the colonic microflora to SCFAs (e.g., acetate, propionate, and butyrate) that promote colon health.

Animal nutritionists have concluded that the feeding value of rice hull has low value because of its high fiber content. However, the studies which looked at rice hull as an ingredient to increase fiber in the diet and not a source of available carbohydrates demonstrated that rice hull is a valuable and plentiful source of "roughage." Researchers have attempted to improve feed efficiency of rice hulls by chemical or microbiological modification. These modifications reduce the dietary fiber and increase the available carbohydrates. In these studies, the improvement in Digestible Matter (DM) over the control untreated rice hull has proven that the untreated rice hull still shows significant feed value as a source of indigestible carbohydrate (e.g., Singh & Gupta 1989, Matsumoto et al 1979).

The constituents of dietary fiber in rice hulls are similar to those of ground rice hull made from defatted concentrated rice bran. Rice hulls (husks) are made up of rice fiber (78%) and silica (18%), with other minor constituents.

Rice bran fiber is now in FDA's GRAS Notification as GRAS Notice No. GRN 373

Composition: (moisture free basis)

	Rice Hull	**Rice Bran Fiber**
Cellulose	38%	30%
Hemicellulose	20%	20%
Lignin	22%	20%
Crude Protein	5%	13%
Ash	15%	17%

7.3. Preclinical animal studies of ground rice hulls

Consumption of defatted, heat-stabilized, or raw rice hull has shown no adverse effects on animal health or feed nutritional quality when fed as 20% of the diet of chicks (Adeniji 2010; Campos et al 1987), 25% in lambs (Kinser et al 1988), or up to 40% of the diet of pigs (Sikka 2007).

A summary of studies in animals fed rice hulls in the diet is presented in Table 2.

Table 2. The feeding of rice hulls to animals Species	**Dose, Dietary Concentration and Results**	**Title**	**Species, Strain, Sex, Age, Number of Animals and Duration**	**Reference**
Cattle	50% ground husks	Evaluation of fungal cellulases in rice hull base diets for ruminants	6 bullocks	Daniels & Hashin 1977
Cattle	Weight gain=34 kg, DM=3. 16kg/100kg, TDN=31%, Daily N Retention=10g	Influence of rice husk as a roughage substitute on the growth and nutrient utilization in Hariana X Jersey calves	16 calves 14 months old 275 days.	Gupta et al 1977
Cattle	DM intake=2 kg/100kg body wt. Gain=422 grams/day. DM digestibility=48%	Utilisation of ground rice husks enriched with urea and molasses as cattle feed.	12 bulls aged 2. 5 years fed for 6 months	Joshi & Khan 1984
Cattle	70% roughage: 30% concentrate; 50% of roughage was rice husk. DM was 48. 3%	Performance of Adult Dairy Cattle maintained on Rice Husk-based and wheat-straw based complete feeds	19 days adult dairy cattle.	Khokahar et al 1984
Cattle	Feed conversion, protein retention efficiency, gross energetic efficiency was not significantly affected by diet.	Effect of feeding alkali-treated rice husk on growth body composition and nutrient utilization in crossbred cattle	20 crossbred calves.	Singh & Gupta 1989

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Cattle	Feed conversion, protein retention efficiency, gross energetic efficiency was not significantly affected by diet.	Effect of feeding alkali-treated rice husk on the Utilization of nutrients by crossbred cattle	12 Karan-Fries fistulated adult animals. 20 days	Singh & Gupta 1990
Cattle	Feed conversion, protein retention efficiency, gross energetic efficiency was not significantly affected by diet.	Digestibility and nutrient utilization efficiency in crossbred calves as influenced by feeding alkali treated rice husk with or without urea	5 male calves 178 days.	Singh & Gupta 1987
Cattle	Feed conversion, protein retention efficiency, gross energetic efficiency was not significantly affected by diet.	Changes in rumen volume, metabolites and blood urea on feed of alkali treated rice husk in cattle	12 fistulated male calves 20 days.	Singh & Gupta
Cattle	Increasing proportion of roughage in the diet exponentially reduces transit time of maize residues in the reticulo-rumen without affecting transit time in the postgastric segments.	The flow of undigested corn residues through the gastrointestinal tract of cattle.	81 Hereford steers 195 kg.	Wylie et al 1990
Cattle	weight gain 1. 83 kg weekly, Daily Dry Matter intake 8. 5, DM digestibility 48. 3%	Roughage-based complete feed for growing calves	Calves for 90 days	Khokahar et al
Cattle		Diets on Animal Performance and Carcass Characteristics Effect of Various Roughages in High Concentrate Beef Cattle		McCartor et al 1972
Cattle		Studies on the use of rice hulls in feeds	7 cows 15 days	Sato & Awaya

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Goat	The result suggests that the diet of goats can be composed of 12.5% feather meal plus 12.5% rice husk with encouraging results in all the parameters studied.	Performance Characteristics of Goat fed Trichoderma treated Feather Meal-Rice Husk Mixture	Twelve West African Dwarf goats (10.0±3.5 kg BW)	Belewu et al 2009
Horses	DM, protein, gross energy, NDF, ADF, hemicellulose and lignin were not different.	Influence of yeast culture supplementation on ration digestion by horses	4 Quarter horse geldings 3 years old, 10 days feed, 5 days collection, 3 days rest.	Hall et al 1999
Mouse	These results suggest that the radioprotective effect of flavonoids in mice may be attributed to the hydroxyl radical scavenging potency in a direct or an endogenous enzyme mediated manner	Radioprotective effect of antioxidative flavonoids in gamma-ray irradiated mice	11 week-old male ICR mice fed 6 hours prior to γ-radiation	Shimoi et al 1994
Mouse	These results suggest that plant flavonoids, which show antioxidative potency in vitro, work as antioxidants in vivo and their radioprotective effects may be attributed to their scavenging potency towards free radicals such as hydroxyl radicals. Therefore, the flavonoids contained in tea, vegetables and fruits seem to be important as antioxidants in the human diet	Radioprotective effects of antioxidative plant flavonoids in mice	11 week-old male ICR mice fed 6 hours prior to γ-radiation	Shimoi et al 1996

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Poultry	No effect was found in protein retention on increasing the dietary level of rice husk in the diets.	Effects Of Dietary Grit Inclusion On The Utilization Of Rice Husk By Pullet Chicks	Two hundred and forty, one day old pullet chicks.	Adeniji 2010
Poultry	given a diet with 0%, 6%, 11% rice husks. No significant difference in weight gain or feed efficiency	Effect of adding rice husks to a diet based on rice for fattening chickens	7 weeks	Campos et al 1987
Poultry	fed 0% 10% 20% rice hulls. Digestibility 69, 77, 80 DM 79, 77, 72; protein 86, 87, 88%.	Effect of fibre of paddy rice on the digestibility of nutrients in diets for fattening chickens.	9 week old chickens	Campos et al1987
Poultry	Hull inclusion did not affect pH of the digestive tract. Chicks might require a minimal amt. of fiber in the diet to stimulate the development of the upper GI tract.	Effects of fiber source and heat processing of the cereal on the development and pH of gastrointestinal tract of broilers fed diets based on corn and rice.	12 chicks 22 days.	Gonzalez-Alvarado et al 2008
Poultry	Rations=0,200,400,600 g/kg rice husk (RH). At day 42 600 g/kg RH reduced wt. compared to other groups. RH is a good nutrient in gees diet and 40% RH is optimal for breeding geese.	Effects of rice husk diluted dietary switching on the phenotypic change of gastrointestinal tract in adult ganders	96 adult ganders 140 day old.	Lu et al 2011
Rabbit	The type of diet did not affect milk DM, crude protein, fat and energy concentrations, the mean values being 287·8, 116·1, 134·2 g/kg and 27·73 MJ/kg, respectively.	Effect of diet and of remating interval on milk production and milk composition of the doe rabbit	73 lactations of 46 Californian × New Zealand does.	Fraga et al 1989

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Rabbit	10% crude fiber. 60% of the diet supplied by rice hulls. Mean retention time for rice hull was 21. 3 hours.	Effect of type of fiber on the rate of passage and on the contribution of soft feces to nutrient intake of finishing rabbits	130 New Zealand rabbits	Fraga et al 1991
Rabbit	Neither the size nor the weight of litters was significantly affected by the type of diet during lactation.	Effect of diets with different digestible energy content on the performance of rabbit does	192 lactations from a total of 59 New Zealand × Californian rabbit does	Pascual et al 1999
Rabbit	Rice hulls had highest digestibility		175 New Zealand rabbits.	Perez de Ayala et al 1991
Rat	Mild acid treatments of lignocellulosic materials result in hemicellulose conversion into sugar and sugar oligomers as well as in solubilization of phenolic compounds with potential food applications. The effect of the operational conditions (measured by the severity factor) on the yield of soluble phenolics and the utilization of these compounds (with antioxidant and antimicrobial activities) as food additives are reviewed. Additional information on other biological effects of phenolics that could be of interest for the formulation of functional foods is provided	Antioxidant activity of byproducts from the hydrolytic processing of selected lignocellulosic materials	White albino rats (Rattus norvegicus)	Garrote et al 2004

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Rat			White albino rats (Rattus norvegicus)	Kim
Rat	The protective effect was noted at 25% and 10% levels, and was not due to abrasive action of the hulls.	Prolonged Effect on Caries of Short-Term Feeding of Rice Hulls to Cotton Rats	Cotton rats (Sigmodon hispidus) 12 day old weanlings 98 days	Madsen & Edmonds 1963
Rat	The protective effect was noted at 25% and 10% levels, and was not due to abrasive action of the hulls	Short assay periods and restricted feeding procedures in caries assays with cotton rats	Cotton rats (Sigmodon hispidus) 12 day old weanlings 98 days and 28 days	Madsen & Edmonds 1967
Rat		Feeding of hydrolyzed rice hull to rats and its digestibility	White albino rats (Rattus norvegicus)	Matsumoto et al 1979
Rat	Rice hulls were no more irritating than bran or regenerated cellulose. Digestibility was approximately 20%.	Cellulose in the Diet of Rats and Mice	12 Female, 18 female rats fed for 36 weeks	McCay 1934
Rat	The rice husk comprised 10% of the rat's diets, the rest were 50% maize, 20% soybeans, 19% sorghum brewer's dried grain, 0. 5% salt and 0. 5% vitamin-mineral premix. The weight gain for rats fed a diet containing 20% acid detergent fiber and untreated raw rice husk was 0. 71 grams/day and the growth rate was 35-43%.		White albino rats (Rattus norvegicus)for 56 days	Belewu et al 2004
Rat		Chemical-bromatologic composition and nutritive value of rice hull (Effects of milling) [for animal	White albino rats (Rattus norvegicus) for 56 days	Gonzalez et al1981

		feeding]		
Rat		Physiological responses of rats to high-fiber biscuits diets containing several sources of hulls or bran		El-Soukkary et al. 1998
Sheep		Effect of rice husks addition in rations of lactating ewes of Etawah grade on growth rate of their off springs		Pongsapan et al 1992
Sheep	Feed intake 765g/day.	Utilization of rice hulls as a ruminant feed part 3	13 wk Merino sheep 24 kg body wt.	Choung & McManus 1976
Sheep	Rice hulls can be fed to sheep up to 25% of the total diet	Low quality roughages in high-concentrate pellet diets for sheep.	16 Rambouillet rams (55 kg), 16 Dorset lamb rams (24 kg).	Kinser et al 1988
Sheep	Diet had no effect on lambing percentage, lamb birth weight, or growth rate.	Rice hulls in ruminants feeding	57 Awassi ewes 2-3yrs. 14 weeks.	Mohammed et al 1987
Sheep	DM digestibility=80, Organic matter dig. =83. Conclusion: 10% rice husks in diet.	Rice husks in animal feeding 4. In vivo digestibility and rate of passage in sheep.	5 Manchega wethers.	Gonzalez et al
Sheep	Ground Hull (GH), Unground Hull (UH)Digestibility: DM=20,20 ORGANIC=14,13 PROTEIN=36,37 Total Digestible Nutrients=27,34	The nutritive and feeding value of lucerne hay, untreated and urea tread straws and rice hulls.	16 wethers	Nik-Khah et al 1992
Sheep	0%, 5%, 10%, 15%, 20% rice hulls. Rumen retention time=33,54,68,70,73 h	The effects of rice hulls on reticulo-rumen retention and feed intake in wethers	Fistulated wethers	Toyokawa & Fukushi

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Sheep		Effect of rice husks addition in rations of lactating ewes of Etawah grade on growth rate of their off springs		Pongsapan et al 1992
Swine	Growing finishing pigs fed diets with 40 percent paddy showed similar performance as pigs fed control diet containing 50 percent maize.	Effect of replacement of maize and rice bran with paddy on the growth performance and carcass traits of growing finishing pigs	Twenty piglets of 2½ months age of similar body weight	Sikka 2007
Swine	Beginning wt=74kg Ending wt=117.	Effect of dietary fiber on fat in low-crude protein, crystalline amino acid-supplemented diets for finishing pigs	64 barrows.	Knowles et al 1998

Other studies also reported that rice hull, corn, and other types of hulls (oat or wheat hull) and ground rice hulls elicited comparable weight gains in rats (Belewu et al 2004), mice (Shimoi et al 1996), geese (Lu et al 2011), and chicks (Gonzalez-Alvarado et al 2008). The pioneer nutritionist, Clive McCay at Cornell University, used ground rice hulls in his classic studies on the importance of cellulose addition in rats (McCay 1934).

7.4. Antimutagenic, antigenotoxic, and anticarcinogenic activities of rice hull

There is no evidence that rice hulls are carcinogenic or mutagenic. On the contrary, rice hulls have been reported to show anticarcinogenic and antimutagenic activities in vitro and in vivo. Rice hulls have been reported to possess an antioxidant effective against lipid oxidation, but also reversing the effects of "inflammation and carcinogenesis."

Table 3 Studies which have been conducted on the Antioxidant Constituents of rice hulls

Table 3: Antioxidant Constituents of rice hulls

Reference	
Jeon et al 2006	Methanol extracts of rice hulls possess significant reactive oxygen activity scavenging and metal chelating activities and protective against oxidative DNA damage using human lymphocytes
Butsat & Siriamornpun 2010	Rice bran and husk can be considered as valuable sources of bioactive components with high antioxidant properties
Haliwell	Free radicals and antioxidants in food and in vivo: what they do and how they work
Nam et al 2004a	Effect of rice hull extract on lipid oxidation and volatiles of cooked

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	turkey meat To be used as natural antioxidants in meat and meat products
Nam et al 2004b	Far-Infrared radiation increases the antioxidant properties of rice hull extract in cooked turkey meat
Ramarathnam et al 1988	Chemical studies on novel rice hull antioxidants 1 Isolation, fractionation, and partial characterization
Ramarathnam et al 1989	Chemical studies on novel rice hull antioxidants
Kim et al 2007	Cytotoxic and antitumor activity of momilactone B from rice hulls
Hyon & Chung 2004	Cyanidin and malvidin from O sativa cytotoxicity against human monocytic leukemia cells by arrert of G 2/M phase and induction of apoptosis
Huang et al 2005	Inhibitory effects of a rice hull constituent on tumor necrosis factor alpha, prostaglandin E2, and cyclooxygenase-2 in lipopolysaccharide-activated mouse macrophages
Juong et al 2008	Enhancement of hypoxia-induced apoptosis of human breast cancer cells via STAT5b by momilactone B
Kim et al	Evaluation of Biological Activities of rice Husk Extracts
Cho et al 1998	Antimicrobial activity of 4-hydroxybenzoic acid and trans 4-hydroxycinnamic acid isolated and identified from rice hull
Lin et al 2002	Prevention of cellular ROS damage by Isovitexin and related flavonoids
Moon et al 2002	Antioxidant compounds of Oryza sativa
Thawornchinsombut & Sripui 2008	Application of rice hulls for natural antioxidant extraction
Rodriguez-Vazquez & Areyzaga 1993	Isolation of lignin from rice hull
Salanti et al 2010	Antioxidant Activity of lignins from rice husk
Ramarathnam et al 1995	The contribution of plant food antioxidants to human health
Osawa et al 1985	Antioxidative defense systems in rice hull against damage caused by oxygen radicals
Butsat et al 2009	Changes in phenolic acids and antioxidant activity in Thai rice husk at five growth stages during grain development

Structural Characterization and Antioxidant Activity Evaluation of Lignins from rice Husk

In recent years, lignin and extractives from herbaceous plants and crops are receiving increasing attention for their renewability and large annual biomass stock. It is worth noting that only a few studies deal with the chemical characterization of rice husk, a side product of one of the most important crops with regard to human nutrition. Thus, in this study lignin from rice husk was isolated and characterized. Two different extraction procedures were optimized and tested: acidolysis and alkaline enzymatic (AE). The different lignins isolated were fully characterized by means of gravimetric, chromatographic (GPC), and spectroscopic (^{31}P NMR, 2D-HSQC-NMR) analyses with the aim to compare yields, sample purity, and chemical properties, recognized as key parameters for future development. Notwithstanding the extraction procedure, the results highlighted that rice husk lignin is mainly formed by guaiacyl and p-

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hydroxyphenyl units. The acidolytic approach showed an appreciable lignin recovery and high purity, whereas the AE lignin sample was found to be rich in residual polysaccharides and oxidized functionalities. Moreover, different rice husk extracts, along with acidolysis lignin and AE lignin specimens, were assayed for their antioxidant activity by means of a DPPH radical scavenging test. (Lee, et al. 2004)

Xylooligosaccharides and Fructooligosaccharides Affect the Intestinal Microbiota and Precancerous Colonic Lesion Development in Rat

Certain nondigestible oligosaccharides can be selectively utilized by probiotics and reduce the risk of colon cancer. However, the inhibitory effects of xylooligosaccharides (XOS) on colon cancer are not well documented. This study evaluated the effects of xylooligosaccharides and fructooligosaccharides (FOS) on the alteration of cecal microbiota, cecal pH, cecal weight, and serum lipid levels, and also their inhibitory effect on precancerous colon lesions in male Sprague-Dawley rats. The rats were randomly assigned to 4 groups: control, treatment with 1, 2-dimethylhydrazine (DMH) [15 mg/ (kg body wt · wk) for 2 wk], treatment with DMH + 60 g XOS/kg diet, and treatment with DMH + 60 g FOS/kg diet. Rats were fed the experimental diets for 35 d, beginning 1wk after the second dose of DMH. Both XOS and FOS markedly decreased the cecal pH and serum triglyceride concentration, and increased the total cecal weight and bifidobacteria population. XOS had a greater effect on the bacterial population than did FOS. Moreover, both XOS and FOS markedly reduced the number of aberrant crypt foci in the colon of DMH-treated rats. These results suggest that XOS and FOS dietary supplementation may be beneficial to gastrointestinal health, and indicate that XOS is more effective than FOS.

Isovitexin, isolated from rice hull of *Oryza sativa*, has been characterized as a potent antioxidant. Its antioxidant activity, determined on the basis of inhibition of lipid peroxidation by the Fenton reaction, was comparable with that of α-tocopherol, a well-established antioxidant. Isovitexin was able to reduce the amount of hydrogen peroxide production induced by lipopolysaccharide (LPS) in mouse macrophage RAW264. 7 cells. In this study, we assessed its effects on the production of tumor necrosis factor α (TNF-α), prostaglandin E2 (PGE2), and the expression of cyclooxygenase-2 (COX-2) in LPS-activated RAW 264. 7 macrophages. Isovitexin inhibited the release of TNF-α, a proinflammatory cytokine, upon LPS activation with a 50% inhibitory concentration (IC50) of 78. 6 μM. Isovitexin markedly reduced LPS-stimulated PGE2 production in a concentration-dependent manner, with an IC50 of 80. 0 μM. The expression of COX-2 was also inhibited by isovitexin treatment. Our results suggest that suppression of ROS-mediated COX-2 expression by isovitexin is beneficial in reducing inflammation and carcinogenesis.

7.4 Adsorption of Heavy Metals by Rice Hulls

It has been found by several researchers (Table 4) that the porous nature of rice hulls actually adsorbs certain compounds, particularly toxic substances such as pesticides and heavy metals. The combination of Antioxidative properties reduces oxidative stress, while heavy metal adsorption prevents further lipid oxidation and heavy metal toxicity.

Reference	**Table 4: Studies on the Removal of Heavy Metals with Rice Hull**
Gupta et al 2009	Removal of lead from aqueous solution by hybrid precursor prepared by rice hull
Asadi et al 2008	Modification of rice hull sorptive characteristics for removing heavy metals from synthetic solutions and wastewater
Evans et al	Use of rice milling byproducts hulls and bran to remove toxic metals

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1993	from aqueous solutions
Roy et al 1993	Absorption of heavy metals by green algae and ground rice hull
Tiwari & Lee 2007	Biosorptive behavior of rice hulls for Ca-134 from aqueous solutions: a radiotracer study
Kayal et al 2010	Application of rice husk for the removal of heavy metals
Feng Q et al 2004	Adsorption of lead and mercury by rice husk
Ye et al 2010	Adsorptive removal of Cd (II)using rice husk
	Biosorption of heavy metals using rice milling byproducts

8. Allergenicity

While rice allergens are seen in Asia, they are almost unknown in the USA and Europe. Rice ingredients are used in gluten-free formulations since they do not contain gluten. Ground rice hulls are low in protein, the source of allergens. RIBUS monitors the allergens present in its products and consistently find the amount of allergens below the detectable level.

9. Summary

Rice hulls have been fed to animals since the beginning of rice cultivation, around 6,000 years ago. Anthropologists have found rice hulls in the dung of ancient animals, as well as humans. The effects of feeding rice hulls to animals have been studied in rats, chicken, sheep, pigs, rabbits and cattle. While the studies focused on the nutritional effect, no adverse events related to the consumption of rice hull fiber were reported in any of these animal studies. These studies demonstrate that the consumption of rice hulls by these animals is safe.

RICE AND FOOD SAFETY

"In many regions of the world, rice is the most important part of the human diet, so the consumer's daily bowl of rice needs to be safe and of good quality. Appropriate good agricultural practices need to be applied when growing rice and controlling pests. After harvesting, efficient on-farm processing, storage and distribution should ensure that the quality does not deteriorate through, for example, the growth of fungi resulting from inadequate drying of the grain. In 1995, the Codex Alimentarius Commission agreed to adopt safety and quality criteria for the rice that is produced for human consumption (Codex Standard for rice). Other Codex work sets maximum limits for pesticide residues and discusses possible limits for certain heavy metals such as cadmium and mycotoxins. These standards for rice are accepted by the World Trade Organization (WTO), so the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) take care to ensure that they have a sound scientific basis.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Expert Meeting on Pesticide Residues address the issues that influence the safety and quality of rice. Their work

includes advising member countries and Codex on good agricultural and manufacturing practices for growing and processing rice. " FAO 2004 "International Year of rice: rice is Life"

RICE FIBER

There is an extensive literature on the antioxidant properties of constituents of rice hulls (husks) and their benefits to human nutrition. Patents have been filed describing fiber constituents of rice hulls and their use in improving the fiber status of a population already low in fiber.

Manufacturers and government agencies, including FAO, have stated that although rice hulls are normally removed before consumption they may be ground in preparation to enrich food.

During milling of cereal grains to refined flours, the outer fiber-rich layers are removed, resulting in a lower content of total dietary fiber. This reduction is due mainly to a decrease of insoluble fiber. The dietary fiber composition in both whole-grain and refined flours is different. Refined flours of oats, barley, rice and sorghum contain mainly glucans, while arabinoxylans dominate in refined flours of wheat, rye and maize. Whole-grain flours all contain considerable amounts of cellulose. The husk which surrounds barley, rice and oats also contains considerable amounts of xylans. This fraction is generally removed before consumption, but oat and rice husks are used for fiber preparation to enrich foods. Carbohydrates in human nutrition. (FAO Food and Nutrition Paper-66)Report of a Joint FAO/WHO Expert Consultation, Rome, 14-18 April 1997 Reprinted 1998, ISBN 92-5-104114-8)

Acute toxicity studies demonstrate that silicon dioxide and silica have moderate to low acute toxicities. An acute oral LD_{50} study (rat) with silicon dioxide resulted in an LD_{50} value of 3160 mg/g; this value is considered Toxicity Category III.
In all these studies, there was no discussion on adverse effects or safety risks in consuming the insoluble rice hulls.
Food Chemicals Codex has listed rice hulls for use in fruit juice under their Good Manufacturing Practices as a Processing Aid.
CODEX GENERAL STANDARD FOR FRUIT JUICES AND NECTARS, (CODEX STAN 247-2005);
PROCESSING AIDS—Maximum Level of Use in line with Good Manufacturing Practices (GMP)
Rice hulls have been used as a filtration aid in beer with the understanding that the hulls be sterilized first to reduce the amount of bacteria and yeast.

The safety of rice derivatives in cosmetics.

This report addresses the safety of cosmetic ingredients derived from rice, Oryza sativa. Oils, Fatty Acids, and Waxes: rice Bran Oil functions in cosmetics as a conditioning agent--occlusive in 39 formulations across a wide range of product types: Bran, Starch and Powder. Rice hulls are an abrasive and bulking agent in one formulation. The Cosmetic Ingredient Review (CIR) Expert Panel considered that safety test data available on certain of these ingredients could be extrapolated to the entire group. There were no safety test data available for Hydrolyzed rice Extract and Hydrolyzed rice Bran Extract, but their safety may be inferred from that of the extracts from which they are derived. Current levels of polychlorinated biphenyls (PCBs) and heavy metals in rice-derived ingredients used in cosmetics are not a safety concern. The Panel was concerned, however, that contaminants such as pesticides have been reported in Rice Bran Oil used for cooking. Pesticides and heavy metals should not exceed currently reported levels for rice-derived cosmetic ingredients. The CIR Expert Panel concluded that these rice-derived ingredients are safe as cosmetic ingredients in the practices of use and concentrations as described in this safety assessment.

10. Basis for GRAS Determination

Rice has been cultivated in south eastern Asia since ancient times, where it is one of the oldest food crops.

Rice hulls have been consumed by animals and humans since the beginning of cultivation (approximately 4000 BC).

Humans have Hand-Pounded rice to remove the hull and the bran, and they have consumed residual hull and bran with no safety concerns.

Rice hulls have been used in Asian Medicine for millennia with no safety concerns.

RIBUS, Inc. utilizes a HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications consistent with Good Manufacturing Practice (cGMP).

Ground rice hull contains insoluble fiber and silica. RIBUS's ground rice hull offers consumers clean, natural, and safe source of dietary fiber. RIBUS's ground rice hull offers consumers clean, natural, and safe alternative to silica.

The Expert Panel has concluded that the proposes uses of RIBUS ground rice hulls, meeting the food grade specifications presented above and manufactured consistent with cGMP are GRAS based on scientific procedures and a history of safe use and therefore is exempt from the premarket approval requirements of the FDCA.

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March 14, 2012

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MAR 14 2012
Division of Biotechnology and GRAS Notice Review

Moraima J. Ramos-Valle, M.S.
Consumer Safety Officer
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
Division of Biotechnology and GRAS Notice Review

Dear Ms. Ramos-Valle

This letter serves as an amendment to the GRAS Notification sent by me to your office on March 1, 2012.

Please add the following uses, included under the regulations pertaining to USDA, for the Ground Rice Hull product included in that Notification:

For use as a free-flow agent in:

Dried Egg Products
- Whole
- Whites
- Yolks

Dehydrated /Dried Beef, Poultry, Pork products
- Fat
- Broth
- Sauces
- Seasonings
- Muscle
- Skin
- Extracts
- Proteins

Thank you,

(b) (6) [redacted]

Neal Hammond
Technical Director
RIBUS
8000 Maryland St. Suite 460
St. Louis, MO 63105

Ramos-Valle, Moraima

From: Neal Hammond [Neal@ribus.com]
Sent: Wednesday, March 14, 2012 11:50 AM
To: Ramos-Valle, Moraima
Cc: Mosley, Sylvester; Carlson, Susan
Subject: RE: GRAS submission "ground rice hull"
Attachments: FDA Amendment 3_14_2012.pdf

Ms. Ramos-Valles,

Attached please find our amendment for added intended use which includes dried egg products and dried meat products. Since these products fall under the jurisdiction of USDA it would be good to send them a copy of our intention to add these ingredients to our GRAS Notification.

Thank you,

Neal Hammond
Technical Director

RIBUS

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neal@ribus.com | ribus.com

2011 Missouri Agriculture Exporter of the Year

From: Ramos-Valle, Moraima [mailto:Moraima.Ramos-Valle@fda.hhs.gov]
Sent: Tuesday, March 13, 2012 5:15 AM
To: Neal Hammond
Cc: Mosley, Sylvester; Carlson, Susan
Subject: GRAS submission "ground rice hull"

Dear Mr. Hammond,

This message is to follow up our telephone conversation yesterday, please send me an amended intended use section reflecting the use on egg products. As Dr. Mosley and I mentioned yesterday this food category/use falls under the USDA jurisdiction, therefore a copy of your GRAS submission for the use of ground rice hull will be sent to USDA for their review according to our Memorandum of Understanding.

You can send a hard copy address to my attention or if you wish you can submit an electronic copy with your signature to me as well.

Please feel free to contact me if you have any questions.

Sincerely,

Moraima J. Ramos Valle, M.S.
Consumer Safety Officer
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
Division of Biotechnology and GRAS Notice Review
Phone: 240-402-1248
Email: Moraima.Ramos-Valle@fda.hhs.gov

SUBMISSION END