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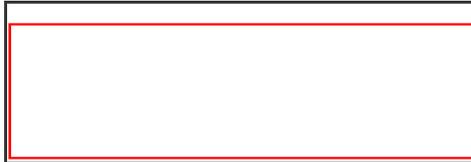
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*NOT ADMITTED IN DC



June 15, 2004

BY FEDERAL EXPRESS

Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration (DBG&R)
5100 Paint Branch Parkway (HFS-255)
College Park, Maryland 20740-3835

Subject: GRAS Notice for Citri-Fi™ Citrus Fiber Products

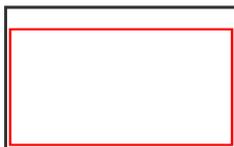
Dear Sir/Madam:

Pursuant to the proposed rule outlined at 62 Fed. Reg. 18939 (April 17, 1997), Fiberstar, Inc. hereby submits notification that the use of Citri-Fi™ Citrus Fiber 100 and Citri-Fi™ Citrus Fiber 200 With Guar Gum products as a moisture retention agent and flavor enhancing agent in foods, including processed meat and poultry products, is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because the notifier has determined that such use is generally recognized as safe (GRAS).

To facilitate your review, this notification is submitted in the format suggested under proposed 21 C.F.R. § 170.36 (c) (see 62 Fed. Reg. at 18961). Four copies of the GRAS Exemption Claim and Additional Information documents, including one for the U.S.D.A. Food Safety Inspection Service, are enclosed. Also enclosed is an electronic copy (Microsoft Word) of the documents.

Sincerely,

Diane B. McColl
Counsel to Fiberstar, Inc.



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GRAS EXEMPTION CLAIM

We hereby claim that the use of Citri-Fi™ Citrus Fiber 100 and Citri-Fi™ Citrus Fiber 200 With Guar Gum as a moisture retention and flavor enhancing agent in foods is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because we have determined that such use is generally recognized as safe (GRAS).

(1) Name and address of the notifier:

Dale Lindquist
President and Chief Executive Officer
Fiberstar, Inc.
3023 15th Street S.W.
Willmar, Minnesota 56201

(2) Common or usual names of the substance that is the subject of the GRAS exemption claim:

Citrus fiber, orange fiber, citrus flour, dried orange pulp, Citri-Fi™

(3) Product description

Citri-Fi™ 100 Citrus Fiber consists of washed orange juice pulp cells (also known as "pulp cells," "juice vesicles" or "pulp") that have been dewatered, sheared, dried and ground to 10 to <200 mesh. Guar gum may be added to the Citrus Fiber at levels up to 33% (2:1 ratio) to produce Citri-Fi™ 200 Citrus Fiber With Guar Gum.

(4) Applicable conditions of use of the notified substance:

(a) Foods in which the substance is to be used:

Citri-Fi™ 100 Citrus Fiber and Citri-Fi™ 200 Citrus Fiber With Guar Gum products are intended for use in baked goods, pastas, salad dressings, confectionery, processed cheese spreads, non-carbonated beverages and juice drinks, and frozen food entrees, such as frozen doughs, frozen meat products, frozen baked goods, frozen desserts, and frozen dairy products. The products are also intended for use in processed meat and poultry products, such as hamburger patty mixes, and in seasoning brines and solutions for meat and poultry products, such as chicken breasts, ribs, pork tenderloins, turkey breasts and beef tips.

000003

(b) Levels of use in such foods:

Citri-Fi™ 100 Citrus Fiber and Citri-Fi™ 200 Citrus Fiber With Guar Gum will be used in foods at levels not to exceed 5%. Use levels in processed meat and poultry products would range from 0.1% to 3%.

(c) Purposes for which the substance is used:

Moisture retention agent, shelf life extension, and flavor enhancing agent.

(d) Description of the population expected to consume the substance:

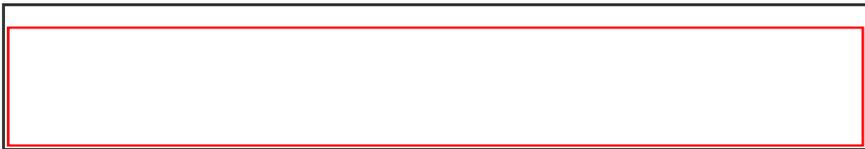
Members of the general population who consume at least one of the food categories described above.

(5) Basis for the GRAS determination:

The basis of the GRAS determination for Citri-Fi™ 100 Citrus Fiber is through common use in food prior to 1958. The basis of the GRAS determination for Citri-Fi™ 200 Citrus Fiber With Guar Gum is through common use in food and scientific procedures.

(6) Review and Copying Statement:

The data and information that are the basis for Fiberstar, Inc.'s GRAS determination are available for the Food and Drug Administration's (FDA's) review and copying at reasonable times at the offices of the notifier, or will be sent to FDA upon request.



Dale Lindquist
President and Chief Executive Officer
Fiberstar, Inc.

Please address correspondence to:

Diane B. McColl
Hyman, Phelps and McNamara, P.C.
700 Thirteenth Street N.W.
Suite 1200
Washington, D.C. 20005
Phone: 202-737-4291

ADDITIONAL INFORMATION

(1) Identity of the notified substance

(a) Common or usual name

Citrus flour, orange fiber, citrus fiber, dried orange pulp, Citri-Fi™.

(b) Product description

Citri-Fi™ 100 Citrus Fiber consists of washed orange juice pulp cells (also known as "pulp cells," "juice vesicles" or "pulp") that have been dewatered, sheared, stabilized/dried and ground to 10 to <200 mesh. Guar gum may be added to the Citrus Fiber at levels up to 33% (2:1 ratio) to produce Citri-Fi™ 200 Citrus Fiber with Guar Gum.

(c) Method of manufacture

The manufacture of Citri-Fi™ Citrus Fiber begins at the orange juice processing operation where raw oranges are squeezed to separate the orange peel, core, and rag from the juice and pulp cells. The juice and pulp cells are processed through a washing operation where the juice is removed from the pulp through a counter current water washing operation which results in the pulp exiting the process at approximately 1% soluble solids, also known as °Brix. From the juicing operation, the pulp is transferred to the fiber processing operation. At the fiber processing facility, the pulp is collected in a surge tank. From the surge tank the pulp is pumped to a dewatering operation to mechanically remove as much water as possible before drying. The pulp can optionally be stabilized using heat or other means before or after dewatering, although the drying process in itself is a stabilizing process. The dewatered pulp is collected in a surge hopper after dewatering and then pumped into the drying system. The pulp is mechanically sheared to tear apart the fiber structures before it enters into the drying process. The drying system reduces the moisture content of the dewatered pulp down to 2-15% moisture so that it is shelf stable under ambient conditions. From the dryer, the product is collected in a surge hopper where it is stored until it is ground. The product is ground in mill and conveyed to storage silos where it is held until packaging. Prior to shipment, the product is conveyed from the silos, through a screening operation to remove larger particles, to a collection hopper where it drops through a magnet and metal detector and then packaged in either 40-50 pound bags/boxes or large tote bags. The product is labeled as Citri-Fi™ 100 Citrus Fiber. When guar is added to the product, either before or after drying, the product is labeled Citri-Fi™ 200 Citrus Fiber.

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(d) Characteristic properties

The product is a yellowish light and fluffy powder. The specifications for the Citri-Fi™ Citrus Fiber products are listed in (f) below

(e) Any content of potential human toxicants

None.

(f) Specifications for Citri-Fi™ Citrus Fiber products

Citri-Fi™ 100 Citrus Fiber

Granulation:	10 to <200 mesh
pH:	5.5-7.5
Fat, Acid Hydrolysis	1.04%
Carbohydrates, Total	82.2%
Fiber, Total Dietary	73.4%
Soluble fiber	36.0%
Insoluble fiber	37.4 %
Protein by Dumas (F=6.25)	7.47%
Moisture/Vacuum Oven (70C/16hr)	6.84%
Ash Analysis	2.44%
USP Heavy Metals (as Pb)	<10 mg/kg (ppm)

Citri-Fi™ 200 Citrus Fiber With Guar Gum

Granulation:	10 to <200 mesh
pH:	5.5-7.5
Fat, Acid Hydrolysis	1.23%
Carbohydrates, Total	81.9%
Fiber, Total Dietary	74.8%
Soluble fiber	37.9%
Insoluble fiber	36.9%
Protein by Dumas (F=6.25)	7.86%
Moisture/Vacuum Oven(70C/16hr)	6.72%
Ash Analysis	2.30%
USP Heavy Metals (as Pb)	<10 mg/kg (ppm)

(2) Information on any self-limiting levels of use

While the high water-retention capacity of the Citri-Fi™ Citrus Fiber products results in benefits to food products, it also has a self-limiting effect on the amount of Citri-Fi™ Citrus Fiber that can be added to a food without producing a loss of desirable eating qualities.

(3) Probable Consumption of Citri-Fi™ Citrus Fiber

Citri-Fi™ Citrus Fiber products are intended for use as a moisture retention agent at levels up to 5.0% in baked goods, pastas, salad dressings, confectionery, processed cheese spreads and frozen food entrees, such as frozen doughs, frozen meat products, frozen baked goods, frozen desserts and frozen dairy products. Citri-Fi™ Citrus Fiber products are also intended for use at levels up to 2.0% to enhance flavor and "mouthfeel" in non-carbonated beverages and juice drinks. In addition, Citri-Fi™ Citrus Fiber is intended for use as a moisture retention agent at levels ranging from 0.1% to 2.0% in processed meat products, such as hamburger patty mixes, and in seasoning brines and solutions for meat and poultry products, such as chicken breasts, ribs, pork tenderloins, turkey breasts and beef tips.

(4) Detailed summary of the basis for the notifier's determination that a particular use of the notified substance is exempt from the premarket approval requirements of the Federal Food, Drug and Cosmetic Act because such use is GRAS.

(a) Citri-Fi™ Citrus Fiber 100 is GRAS through experience based on common use in foods.

Citri-Fi™ Citrus Fiber consists of juice cells (also known as pulp cells, juice vesicles or pulp) from oranges that have been dried, mechanically sheared and ground. Orange juice cells have been consumed in the human diet for centuries. Oranges are believed to have originated in Southeast Asia and India, were cultivated in Italy by the end of the Roman Empire, and spread to the rest of Europe throughout the Middle Ages. Christopher Columbus brought the first oranges to Florida in 1493. By law, each sailor on every Spanish ship that sailed to the Americas carried 100 seeds with him. Ponce de Leon carried citrus seeds to Florida in 1513 and directed his sailors to plant seeds upon landing (Hui, 1999). Anson Van Leuven brought the first orange trees to the California San Bernardino Valley in 1857 (National Orange Show Foundation, 2004). In 1893, the U.S. Department of Agriculture (USDA) initiated the systematic breeding of sweet oranges in Florida (Hui, 1999).

Recipes for the use of oranges in foods can be found in several historical cookbooks. *Culinary Chemistry*, published in 1821 by Fredrick Accum, contains a recipe for orange marmalade (Kansas State University Library, 2003). One of the first cookbooks published in 1872 in California, *How to Keep a Husband or Culinary Tactics*, included a recipe for boiled orange pudding (Seasonal Chef, 1997). Among the food recipes for oranges that were popular during the Civil War period are dessert recipes for orange custard and General Robert E Lee Lemon-Orange Cake Frosting (The Civil War Zone, 2004; The Washington Artillery of New Orleans - 5th Company and The 6th Massachusetts Light Artillery, 2004). Published in conjunction with the 1928 San Bernardino Orange Festival, the *Nellie Aldridge's National Orange Show Cookbook* provides numerous recipes for oranges in foods, such as "Sunny Southern Preserved Oranges," "Creole Oranges," "Orange syrup," "Orange Sauce for Duck" and "Bacon and Oranges" (Seasonal Chef, 1999).

Today, oranges are the most consumed fruit in America. In the year 2000, the per capita orange consumption in the United States was 91.5 lbs (USDA 2002). The typical American consumed 5.8 gallons of orange juice, equal to 79.5 pounds of fruit, and an average of 12 pounds of fresh oranges. A typical orange contains has 4-5 g juice cells (the 4-5 g are @ 95% MC) per 100 g fruit (Braddock, 1983, 1999).

The only processing aid used in the production of Citri-Fi™ Citrus Fiber is water, and the final product meets appropriate food grade specifications. A thorough review of the publicly available scientific literature revealed no evidence of any adverse effects associated with Citrus Fiber. In addition, an independent scientific expert qualified by training and relevant national and international experience to evaluate the GRAS status of food and food ingredients, critically evaluated the available pertinent data and information and concluded that other qualified experts would agree that, under the conditions of intended use, Citri-Fi™ Citrus Fiber 100 is GRAS through experience based on common use in foods. See attached confidential GRAS opinion.

(b) Citri-Fi™ Citrus Fiber 200 with Guar Gum is GRAS based on scientific procedures (guar gum) and through experience based on common use in foods (Citri-Fi™ Citrus Fiber).

As described in (a) above, the Citrus Fiber ingredient in Citri-Fi™ Citrus Fiber 200 is GRAS based on experience through common use in foods. The guar gum ingredient meets applicable Food Chemicals Codex specifications and is affirmed as GRAS by FDA for use in numerous foods at levels up to 2% in the finished food. See 21 C.F.R. §184.1339. The amount of guar gum in foods resulting from addition of Citri-Fi™ Citrus Fiber 200 would be comparable to that affirmed as GRAS by FDA. Thus, as evidenced in the attached, independent qualified scientific experts would agree that, under the

conditions of intended use, Citri-Fi™ Citrus Fiber 200 is GRAS based on scientific procedures and through experience based on common use in foods. See attached confidential GRAS opinion.

(5) References

- Braddock, R.J. (1983). Utilization of citrus juice vesicle and peel fiber. *Food Technology*. Dec. 1983:85-87.
- Braddock, R.J. (1999). *Handbook of Citrus By-Products and Process Technology*. Florida Agricultural Experiment Station Journal Series No. R-067467. John Wiley and Sons, Inc. New York, NY.
- Hui, S. (1999). Sweet oranges: The biogeography of *Citrus sinensis*. Retrieved from <http://www.aquapulse.net/knowledge/orange>.
- Kansas State University Library (2003). Rare Books, Fredrick Accum, *Culinary Chemistry* (London:Ackermann), 1821. Morse Dept. of Special Collections. Retrieved from <http://www.lib.ksu.edu/depts./spec/rarebooks/cookery/accum1821.html>.
- National Orange Show Foundation (2004). History of the National Orange Show. Retrieved from <http://www.nationalorangeshow.com/history.htm>.
- Seasonal Chef (1999). Five orange recipes from yesteryear. Retrieved from <http://www.seasonalchef.com/preserves17.htm>.
- Seasonal Chef (1997). To keep a husband, try pudding. Retrieved from <http://www.seasonalchef.com/historical1.htm>.
- The Civil War Zone (2004). Dessert Recipes. Retrieved from <http://www.civilwarindex.homestead.com/DessertRecipes~ns4.html>.
- The Washington Artillery of New Orleans-5th Company and The 6th Massachusetts Light Artillery (2004). Recipes, foods, and remedies: D to G. Retrieved from <http://www.geocities.com/Heartland/Woods/3501/recipes.htm>.
- US Dept. of Agriculture (USDA) (2002). *Fruit and Tree Nuts Outlook*. FTS-296/ Jan. 31, 2002. USDA Economic Research Service, Washington, D.C.

Pages 000010-000011 removed under the Privacy Act of 1974.

SUBMISSION END

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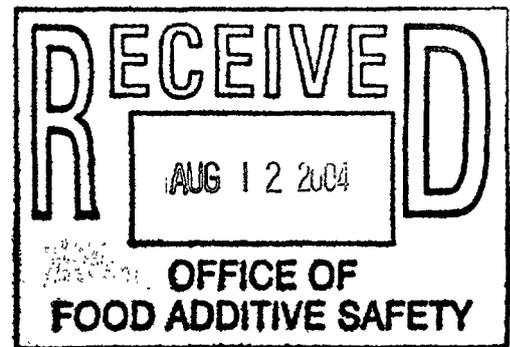
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August 9, 2004

BY HAND DELIVERY

Dr. Susan Carlson
 Office of Food Additive Safety
 Center for Food Safety and Applied Nutrition
 U.S. Food and Drug Administration
 5100 Paint Branch Parkway
 College Park, Maryland 20740-3835



Re: Supplement to GRN No. 000154

Dear Dr. Carlson:

Pursuant to your telephone conference with Brock Lundberg of Fiberstar, Inc., (Fiberstar) and Paul Hyman of this firm, Fiberstar submits this supplement of further data and information to the above referenced GRAS Notice for Citri-Fi™ Citrus Fiber products, filed on June 21, 2004.

First, Fiberstar agrees that the basis for the generally recognized as safe (GRAS) determination of both Citri-Fi™ 100 Citrus Fiber and Citri-Fi™ 200 Citrus Fiber is through scientific procedures as well as common use in food. The GRAS opinion of Dr. Joseph F. Borzelleca and the accompanying scientific data and information apply to both Citri-Fi™ products.

Second, Fiberstar waives its claim of confidential business information for the GRAS opinion letter from Dr. Joseph F. Borzelleca included in the GRAS Notice. Enclosed is a copy of his expert opinion that may be placed on public display.

000019

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Third, the maximum usage level of the Citri-Fi™ Citrus Fiber products in processed meat and poultry products is 3%, as stated in the GRAS Exemption Claim, Section 4(b) (page 2). The reference to 2% maximum use in such products in Section 3 (page 3) of the Additional Information document should be changed to 3%.

Fourth, we have calculated the levels of pulp consumed in orange juice and oranges in comparison with estimated consumption from use of the Citri-Fi™ Citrus Fiber products in breads. As noted in Dr. Borzelleca's letter, individuals in the United States consume an average of 5.8 gal (48.72 lb) of orange juice, which is the equivalent of 79.5 lbs of fruit, and 12 lbs of fresh oranges annually (USDA Economic Research Service, 2002) (enclosed with GRN 154 filed June 21, 2004). According to Braddock (1999) (enclosed), 90 lbs of oranges (frequently referred to as a box of oranges) contain 8 lbs of pulp on a wet basis. Assuming that the pulp is at 94% moisture, the 90 lbs of fruit contains 0.522 lbs (237 g) of dry pulp fiber when dried down to 8% moisture. If a person consumed orange juice with 50% of the total pulp removed from the juice, he would consume 0.231 lbs (105 g) of pulp at 8% moisture annually from orange juice. He would also consume 0.0696 lbs (31.6 g) of pulp at 8% moisture annually from fresh oranges. Adding the total from orange juice and fresh oranges, the total pulp per capita adds up to be close to 0.301 lbs (137 g) annually at 8% moisture.

According to the USDA Economic Research Service (Winter 2002) (enclosed), the annual per capita consumption of flour in 2000 was 146.3 lbs. Based on an estimated U.S. population of 290,000,000, the total annual consumption of flour is 42.4 billion pounds. If Fiberstar attains 5% of the total U.S. flour market at the maximum usage level in flour of 3%, almost 63,700,000 lbs of Citri-Fi™ would be consumed per year, representing an annual per capita consumption of 0.219 lbs (99.4 g) Citri-Fi™. Fiberstar expects that 10% of such Citri-Fi™ use would consist of the guar gum ingredient and the remaining 90% would be orange pulp fiber. This breaks down to a per capita consumption estimate of 0.0219 lb/yr (9.94 g/yr) guar gum and 0.198 lb/yr (89.9 g/yr) pure orange pulp fiber.

Here is an example that illustrates the consumption estimate: from two 8 oz glasses of orange juice with no pulp added or removed, a person consumes 16 oz or 448 g of juice, and $448 \text{ g of juice} \times (79.5 \text{ fruit}/48.7 \text{ juice}) = 731 \text{ g fresh fruit}$, and $731 \text{ g fruit} \times (0.522 \text{ g dry pulp}/90 \text{ g fresh fruit}) = 4.24 \text{ g of pulp at 8\% moisture in 16 oz of orange juice}$. To consume the same 4.24 g of pulp fiber from bread containing a typical level of 1.5% Citri-Fi™, a person would have to consume: $4.24 / 0.015 = 283 \text{ g or } 10.1 \text{ oz of bread}$, which is slightly over 10 typical slices of bread.

Dr. Susan Carlson
August 9, 2004
Page 3

HYMAN, PHELPS & MCNAMARA, P.C.

Finally, as requested, Fiberstar's Citri-Fi™ products have been analyzed for lead (Pb) content. Based on the results of those tests, the specifications for "USP Heavy Metals (as Pb)" for the two substances should be revised to "< 0.5ppm." See Additional Information, Section (1)(f), page 2.

Please let us know if you need any further information concerning the GRAS notice for Fiberstar's Citri-Fi™ products.

Sincerely,

Diane B. McColl

DBM/dmh.
Enclosure

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Pages 000022 - 000036 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

JOSEPH F. BORZELLECA

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04 June 2004

Mr. Dale Lindquist, President & CEO
Fiberstar, Inc.
3023 15th Street SW
Willmar, MN 56201-9670

Re: Citrus fiber (Citri-Fi 100™) & Citrus fiber and guar gum (Citri-Fi 200™)

Dear Mr. Lindquist:

As an independent scientific expert, qualified by training and relevant national and international experience to evaluate the "generally recognized as safe" ("GRAS") status of food and food ingredients, I have critically evaluated the citrus fiber products manufactured by Fiberstar, Inc. (Fiberstar) and intended for use in foods. Fiberstar produces two citrus fiber products, of which one is 100% citrus fiber ((Citri-Fi 100™) and the other is a combination product consisting of citrus fiber and guar gum (Citri-Fi 200™). Fiberstar's citrus fiber products are intended for use as a moisture retention agent in baked goods and other products at levels up to 5.0%, as a flavor enhancer and to provide "mouth feel" in non-carbonated beverages at levels up to 2.0% and as a moisture retention agent in meat products at levels of 0.1% to 2.0%. There is a self-limiting level of use of citrus fiber in foods due to its high water-retention property.

Determining the GRAS status of a food ingredient requires a critical evaluation of the available information on the ingredient. This includes a comprehensive search of the scientific literature for information and data on the safety of the ingredient and substances closely related to it chemically, as well as consideration of any history of use of the substance, a complete characterization of the product, manufacture and specifications, the conditions of intended uses in foods including levels of use, and estimated dietary intake, and any other data pertinent to safety of the product. Following a critical evaluation of all available information, the expert may conclude that the product is GRAS through scientific principles (critical evaluation of information and data) or through experience based on common use in foods prior to 01 January 1958.

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I have critically evaluated the materials provided by Fiberstar and by Diane McColl, counsel to Fiberstar. These materials included the results of a comprehensive search of the scientific literature through May 2004, characterization of Fiberstar's products, manufacturing/processing information, a description of the intended conditions of use in foods including use levels, and a published paper on the effects of citrus pulp on tumorigenesis and immune response in rats with

000037



colon tumors (the only paper identified in the search of the published literature). Fiberstar's 100% citrus fiber, consists of washed orange juice pulp cells that have been dispersed, pasteurized, dried and ground to 10 to <200 mesh. Water is the only chemical used in the process. There are no potentially toxic substances in the product. The product meets food grade specifications. There are no data in the published scientific literature that indicate or suggest any adverse effects of citrus fiber. Oranges are one of the most widely consumed fruits in America; they are consumed primarily as juice but also as fresh fruit and as an ingredient in other foods. "An average American consumed 5.8 gallons (single-strength equivalent) of orange juice, equal to 79.5 pounds of fruit. Consumed fresh, Americans ate an average of 12 pounds in 2000, still well behind bananas and apples." (Economic Research Service, USDA, 31 January 2002). The United States population has consumed oranges long before 1958. The guar gum in Fiberstar's combination product is affirmed by FDA as GRAS for use in foods under 21 C.F.R. 184.1339 and complies with the applicable Food Chemicals Codex specifications.

Based on my critical evaluation of the available data and information pertinent to safety, I conclude that Fiberstar's citrus fiber is GRAS for its intended use in foods based on the common use of oranges prior to 1958. I further conclude that Fiberstar's citrus fiber/guar gum combination products are GRAS for their intended use in foods through common use in foods and scientific procedures. It is my opinion that other experts, qualified by training and/or experience to evaluate the safety of substances added to food, would concur with my conclusions, namely, that Fiberstar's citrus fiber products are GRAS through experience based on common use in foods prior to 1958 and through scientific procedures.

Thank you for the opportunity to provide assistance.

Joseph F. Borzelleca

000038

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Reference List for Industry Submission, GRN 000154

<i>Pages</i>	<i>Author</i>	<i>Title</i>	<i>Publish Date</i>	<i>Publisher</i>	<i>BIB_Info</i>
000022	Braddock, R. J.	Pulp Washing Process: 7.1.1 FMC Process: 7.1.1.1 Pulp Wash	1999	Handbook of Citrus By-Products and Process Technology. Florida Agricultural Experiment Station Journal	Series Number R-067467, pg 87
000023 - 000036	Putnam, Judy; Allshouse, Jane; Kantor, Linda Scott	U.S. Per Capita Food Supply Trends: More Calories, Refined Carbohydrates, and Fats	2002	FoodReview	Volume 25, Issue 3, pgs 2- 15

NA- Not applicable