Citri-fi®

FIBERSTAR™

January 31, 2008

Robert L. Pooler
Program Manager USDA/AMS/TM/NOP
Room 4008-So, Ag-Stop 0268
1400 Independence Ave SW
Washington, DC 20250

Dear Mr. Pooler:

I have enclosed two copies of Fiberstar Inc.'s petition for the inclusion of dried orange pulp in or on organic products under Section 205.606 of the National List.

Please do not hesitate to contact me directly with any questions, or if I can clarify any information contained in the petition.

Fiberstar, Inc. appreciates your consideration of this petition.

Respectfully submitted,

Brock Lundberg
Vice President of Technology
Fiberstar, Inc.
ph: (715) 273-3194
b.lundberg@fiberstar.net

Fiberstar, Inc.
N5233 US Hwy 63, Ellsworth, WI 54011
Phone (715) 273-3194 • Fax: (715) 273-3147 • E-mail: b.lundberg@fiberstar.net

PETITION TO ADD "DRIED ORANGE PULP" TO THE NATIONAL LIST

TABLE OF CONTENTS

PETITION TO ADD TO THE NATIONAL LIST THE SUBSTANCE "DRIED ORANGE PULP"

Item A

1. Category

Non-organically produced agricultural products allowed in or on processed products labeled as "organic." 7 C.F.R § 205.606.

2. Justification for this category

The petitioned substance is produced from orange juice pulp by washing with water, stabilizing with heat, dewatering, mixing, drying, and grinding. No chemicals are used in the production process. Only water is used for washing and processing the orange pulp. The process is similar to that used in the production of herbs and spices for food use.

Item B

1. The common name of the substance

The dried orange pulp produced by Fiberstar Inc. (Fiberstar) bears the trade name Citri-Fi® 100 and is available in varying particle sizes ranging from 10 mesh to 200 mesh. In this petition, we will refer to the compound as "dried orange pulp." However, other names for the product include citrus fiber and citrus flour.

2. The manufacturer

Fiberstar, Inc.
3023 15th St. SW
Willmar, MN 56201
Ph: (320) 231-1829

3. The intended or current use of the substance

Dried orange pulp is currently used as a moisture retention agent and fat substitute 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 at a maximum use level up to 5 percent. In addition, dried orange pulp may be used as a flavor enhancing agent in non-carbonated beverages and fruit drinks at a maximum use level up to 2 percent, and as a moisture retention agent in processed meat and poultry products and in seasoning brines and

solutions for meat and poultry products at maximum use level of 3 percent. Dried orange pulp may also be used as a processing aid at levels up to 1 percent. Dried orange pulp would be included in organic foods for the same above-described current uses. Levels of use in foods are self-limiting; at higher levels of use there is a loss of desirable eating qualities.

4. The handling activities for which the substance will be used and its mode of action

Dried orange pulp is a powdered food ingredient that is blended into the processed food products using conventional food processing equipment. The function of the dried orange pulp in the finished food system is to retain moisture, reduce syneresis, bind water, reduce ice crystal formation, reduce fat, emulsify, thicken, and enhance flavor.

5. The source of the substance and a detailed petition description of its manufacturing and processing procedures

The manufacture of dried orange pulp begins at the orange juice processing operation where raw oranges are squeezed to separate the orange peel, core, and rag (i.e., the membrane material of the orange) 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. It is important that the pulp be processed immediately after it is squeezed from the oranges to avoid deterioration due to the high moisture content of the pulp.

At Fiberstar's 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 is stabilized using heat before dewatering. The dewatered pulp is collected in a surge hopper and then pumped into the drying system. The pulp is then sent through a mixer and prepared to enter the drying system, which reduces the moisture content of the dewatered pulp down to 1-12% moisture so that it is shelf stable under ambient conditions. From the dryer, the product is collected and stored in a surge hopper until it is ground. The product is ground in a 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. The product is labelled as Citri-Fi® 100 Citrus Fiber. The product can then be further ground to make Citri-Fi 100 products with different particle sizes. For example, the Citri-Fi 100 can be ground to a particle size of 91% less than 100 mesh to make Citri-Fi 100FG or 91% less than 200 mesh to make Citri-Fi 100M40.

The only processing aid used in the production process of dried orange pulp is water. No chemicals are used in the process and no unnatural residues are introduced into the dried orange pulp during the production process. Analyses by an independent laboratory confirm that no pesticide residues are present in Fiberstar's dried orange pulp..

6. A summary of any available previous reviews of the petitioned substance by State or private certification programs or other organizations

No such reviews exist.

7. Information regarding EPA, FDA and State regulatory authority registrations

FDA had no questions in response to Fiberstar's notification of its determination that dried orange pulp is generally recognized as safe (GRAS), based on scientific procedures, under the conditions of intended use in foods. (FDA Response Letter to GRAS Notice No. 000154; see Attachment A).

8. The Chemical Abstract Service (CAS) numbers of the substance

Dried orange pulp does not have an assigned CAS number.

9. The substance's physical properties and chemical mode of action

Dried orange pulp is the dried soluble and insoluble ground solids remaining after juicing oranges. Dried orange pulp contains 33.3 percent soluble fiber and 34.9 percent insoluble fiber for a total dietary fiber content of 68.2 percent. A copy of the technical information sheet for dried orange pulp is enclosed in Attachment B.

Dried orange pulp acts to bind and or stabilize water and/or fat in food systems. The mechanism for the binding is a physical property of the dried orange pulp brought about by its unique structure. The amorphous cell structure of the orange pulp in addition to the natural combination of soluble and insoluble fiber provides it with its high water binding properties. This high water binding capacity serves to stabilize water and fat in meat, bakery, dairy, and many other products in addition to being a natural fat replacer. Due to the soft particles of the dried orange pulp the finished products are not gritty and the taste of the finished product is not compromised.

Dried orange pulp is manufactured from orange juice pulp cells that have been washed with water, dewatered, sheared, stabilized/dried and ground to a particle size between 10 to 200 mesh. No chemical extraction or treatment is involved in the manufacturing process.

Dried orange pulp is biodegradable and does not persist in the environment.

10. Safety information about the substance

The MSDS for dried orange pulp is enclosed with this petition as Attachment C. There is no information available from the National Institute of Environmental Health Studies regarding dried orange pulp.

Dried orange pulp is generally recognized as safe (GRAS) when used in food in accordance with current good manufacturing practice. FDA had no questions in response to the GRAS notice for Fiberstar's dried orange pulp. See FDA response letter in Attachment A. There are no known adverse reactions related to dried orange pulp.

11. Comprehensive research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions

Dried orange pulp is produced under patent protection solely by Fiberstar, Inc. There are no other sources worldwide for dried orange pulp as a functional food ingredient.

Although there are fibers on the National List, these fibers cannot duplicate the functional properties of dried orange pulp. Dried orange pulp is unique because it can bind levels of water up to ten times its own weight. In addition, dried orange pulp can mimic fats and oil in taste, mouthfeel, and freshness. Dried orange pulp does not produce the slimy mouthfeel associated with some other soluble fibers. Because dried orange pulp contains only 33.3% soluble fiber, it has a very clean and natural mouthfeel.

Insoluble fibers, e.g., oat fiber, are available on the marketplace. However, these products do not have the functional properties of dried orange pulp in terms of water and oil binding capacity and viscosity. For example, oat fiber has a water binding capacity of approximately 2-3 times its weight whereas dried orange pulp binds 6.5-10 times its weight in water.

Fiberstar is unaware of any research summaries or bibliographies that present a contrasting position.

12. A "Petition Justification Statement: which provides justification for inclusion of a non-organically produced agricultural substance onto the National List"

The inclusion of dried orange pulp in the National List as a non-organically produced agricultural substance is based on the unavailability of an alternate organic agricultural substance.

Dried orange pulp is derived from orange juice pulp, i.e., the waste stream of orange juice manufacture. The invention of dried orange pulp is intended to allow full use of the byproducts of orange juice production. Before invention of the dried orange pulp production process, the byproducts of orange juice manufacture were sold as animal feed or sent to an approved solid waste site.

Fiberstar processes approximately 10,000 – 20,000 pounds of dry orange pulp per day at its production plant in Clewiston, Florida. The juice production byproduct consists of about 95% water before entering Fiberstar's process. Thus, Fiberstar's production of dried orange pulp from the byproduct eliminates the disposal of approximately 200,000 – 400,000 pounds of waste material.

The production of an organic dried orange pulp is not feasible at this time due to the inadequate supply of organic raw material. The current production facility for dried orange pulp does not have access to a byproduct stream from organic oranges. Also, the existing organic orange byproduct stream is insufficient to support the production of orange pulp as a commercial food ingredient because the total quantity of organic oranges grown is so small. According to data from the USDA Economic Research Service, in 2005, all organic citrus groves in the US totaled a mere 10,152 acres, i.e., significantly less than the 16,500+ acres of orange groves used for the production of orange pulp, the raw material for Fiberstar's process. See http://www.ers.usda.gov/data/organic (updated on Nov. 26, 2007); http://www.southerngardens.com/environment_groves.html.

Although there are approximately 6000 acres of organic orange groves in Florida, use of the orange pulp from these oranges is not feasible due to the inability to economically and safely transport this material with its high moisture content by road. See http://smallfarms.ifas.ufl.edu/organic_production/organic_fruit.html. To begin with, it is not possible to preserve the raw material because the orange pulp will rapidly degrade in its raw form. The 95% moisture and the presence of sugar make the product sensitive to microbial growth. Stabilization of this raw material would be cost prohibitive. Also, the high viscosity of the starting material makes it extremely difficult to pump the material in and out of a truck. Fiberstar built its operation immediately adjacent to an orange juice processor so that the orange pulp can be pumped directly over to its operation. Additionally, assuming the product would be microbiologically stable and would be able to flow in and out of a truck, one truck load of 40,000 pounds of orange pulp would yield only 2,000 dry pounds of finished dried orange pulp material. The resulting costs, including the transportation cost, would be too high to justify production for both Fiberstar as a manufacturer, and for the customer seeking organic products. Placing a dedicated plant at an organic orange juice processing operation would also be cost prohibitive at this time because of the small quantity and small volume of organic oranges currently being processed. However, when in the future the

volume of organic raw material increases to levels similar in size and quality to what Fiberstar requires at its current operation, Fiberstar would seriously consider construction of a dedicated organic dried orange pulp processing operation.

For your convenience of review, a summary of the NOSB evaluation criteria as applied to dried orange pulp is provided in Attachment D.

Attachment A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD 20740

Diane B. McColl
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Washington, DC 20005

DEC 13 2004

Re: GRAS Notice No. GRN 000154

Dear Ms. McColl:

The Food and Drug Administration (FDA) is responding to the notice, dated June 15, 2004, that you submitted on behalf of Fiberstar, Inc. (Fiberstar) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on June 17, 2004, filed it on June 21, 2004, and designated it as GRAS Notice No. GRN 000154.

The subject of the notice is dried orange pulp. The notice informs FDA of the view of Fiberstar that dried orange pulp is GRAS, through scientific procedures, for use as a moisture retention agent 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 at a maximum use level up to 5 percent; for use as a flavor enhancing agent in non-carbonated beverages and fruit drinks at a maximum use level up to 2 percent; and for use as a moisture retention agent in processed meat and poultry products and in seasoning brines and solutions for meat and poultry products at maximum use level of 3 percent.

Fiberstar describes the identity, composition, and method of manufacture of dried orange pulp. Dried orange pulp is manufactured from orange juice pulp cells that have been washed, dewatered, sheared, stabilized/dried and ground to a particle size between 10 to 200 mesh. Fiberstar notes that no chemical extraction or treatment is involved in the manufacturing process, and that the product's final form is a yellowish light and fluffy powder. Fiberstar states that the dried orange pulp final product has a pH of 5.5 to 7.5. The product is 36 percent soluble fiber and 37.4 percent insoluble fiber for a total dietary fiber content of 73.4 percent. Fiberstar provides specifications for the manufactured product.

Fiberstar notes that dried orange pulp has self-limiting levels of use due to the high water-retention capacity of the product. When used above the self-limiting levels of use there is a loss of desirable eating qualities. Such limiting levels are 5 percent for 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; 2 percent for non-carbonated beverages and juice drinks; and 3 percent for processed meat products and in seasoning brines and solutions for meat and poultry products.

Fiberstar estimates the current dietary intake of dried orange pulp consumed from fresh oranges and orange juice and then calculates the additional consumption of dried orange pulp from a proposed additional use. Based on published estimates of fresh orange and orange juice consumption, the annual consumption of pulp at 8 percent moisture per capita would be approximately 0.3 pounds (137 grams). Based on the amount of dried orange pulp that could be added to flour, Fiberstar estimates that approximately 63.7 million pounds of dried orange pulp as added to flour would be consumed per year, resulting in an additional annual per capita consumption of 0.219 pounds (99.4 grams).

Standards of Identity

In its notice, Fiberstar states its intention to use dried orange pulp in several food categories, including foods for which standards of identity exist (i.e., certain bakery products), located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity. If Fiberstar has any questions about the use of dried orange pulp in standardized foods, other than meat or poultry products, that would be marketed in the United States, Fiberstar should contact the staff in the Office of Nutritional Products, Labeling and Dietary Supplements, Division of Standards and Labeling Regulations, HFS-820, 5100 Paint Branch Parkway, College Park, MD 20740. Fiberstar can reach this division by telephone at (301) 436-2371.

Use in Meat and Poultry Products

During its evaluation of GRN 000154, OFAS consulted with the Labeling and Consumer Protection Staff of the Food Safety and Inspection Service (FSIS) of USDA. Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, FSIS is responsible for determining the efficacy and suitability of food ingredients in meat and poultry products as well as prescribing safe conditions of use. Suitability relates to the effectiveness of the ingredient in performing the intended purpose of use and the assurance that the conditions of use will not result in an adulterated product, or one that misleads consumers.

FSIS advises that Fiberstar has provided sufficient data to support their assertion that this ingredient is suitable as a moisture retention agent or as a binder in ground meat and poultry products. Therefore, FSIS would not object to the use of this ingredient as a binder in ground meat and poultry products provided it does not exceed 3.5 percent of the product formulation.

FSIS advises that binders are regulated under the Federal Meat Inspection Act based on efficacy of use in meat products, including standardized meat products. The Federal meat inspection regulations list specific binding additives for use below 3.5 percent of meat product formulation. FSIS has viewed the use of binders and extenders at levels greater than 3.5 percent as recharacterizing products. FSIS would not object to the use of dried orange pulp as a binder in various non-standardized meat and poultry products provided it does not exceed 3.5 percent of the product formulation. Currently, there are no allowances for the use of dried orange pulp as a binder in standardized meat and poultry products.

FSIS also advises that the ingredient will need to be declared on the labeling of meat and poultry products containing it as citrus flour or dried orange pulp.

FSIS requested that FDA advise Fiberstar to seek regulatory guidance from FSIS, Labeling and Consumer Protection staff, about the use of the ingredient in emulsified meat and emulsified poultry products. Fiberstar should direct such an inquiry to Dr. Robert Post, Director, Labeling and Consumer Protection Staff, Office of Policy, Program and Employee Development, Food Safety and Inspection Service, 1400 Independence Ave., S.W., Suite 602, Annex, Washington, DC 20250-3700. The telephone number for that office is (202) 205-0279 and the facsimile number is (202) 205-3625.

Conclusions

Based on the information provided by Fiberstar, as well as other information available to FDA, the agency has no questions at this time regarding Fiberstar's conclusion that dried orange pulp is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of dried orange pulp.

As always, it is the continuing responsibility of Fiberstar to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,

for

Laura M. Tarantino, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

cc: Dr. Robert Post, Director
Labeling and Consumer Protection Staff
Office of Policy, Program and Employee Development
Food Safety and Inspection Service
1400 Independence Ave., S.W., Suite 602, Annex
Washington, DC 20250-3700

Attachment B

FIBERSTAR™

EMERGENCY

PHONE: (320) 231-1829

FIBERSTAR, INC.
3023 15th Street SW
Willmar, MN 56201-9670

Product Name: Citri-Fi® 100

MSDS Number: Citrus Fiber-001 – *Effective Date: March 1, 2002*

1. Product and Company Identification

Product Description: A low-bulk density fiber consisting of citrus fiber that has been processed to enhance its water retention and rheological properties.
Synonyms: None.
CAS No.: Not Applicable.
Molecular Weight: Not applicable.
Chemical Formula: Not applicable.
Product Codes: Citrus Fiber
Company Identification: Fiberstar, Inc., 3023 15th Street SW, Willmar, MN 56201-9670. Phone: (320) 231-1829, Fax: (320) 231-3741.

2. Composition/Information on Ingredients

Hazardous Ingredient	CAS. No.	Percent	Hazardous
None			

3. Hazards Identification

Emergency Overview:
Label Precautionary Statements:
CAUTION: Avoid Contact, Inhalation and Ingestion.
MAY CAUSE IRRITATION, DRYNESS AND DEHYDRATION . TARGET ORGANS: Eyes, Mouth, Respiratory System, Digestive System and Skin.
Potential Health Effects:
Eye Contact: Nuisance dust. May cause irritation and dryness.
Inhalation: Nuisance dust. May cause dryness and irritation to respiratory system.
Ingestion: Non-toxic. May cause dryness in mouth and dehydration.
Skin contact: No known problems due to skin contact. May cause irritation with dryness and abrasion.
Chronic Exposure: No known problems.
Aggravation of Pre-existing Conditions: No known problems.

4. First Aid Measures

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. Get medical advice if irritation develops.
Inhalation: Remove to fresh air. Get medical attention for any breathing difficulty.
Ingestion: If swallowed, wash mouth out with water and give several glasses of water to drink to dilute provided person is conscious. If large amounts were swallowed, get medical advice from a physician.
Skin Contact: Immediately wash skin with plenty of soap and water. Get medical advice if irritation develops.

5. Fire Fighting Measures

Fire: Usual fire hazard.
Explosion: This material, like most materials in powder form, is capable of creating a dust explosion. Emits toxic fumes under fire conditions. Static charge buildup can be a potential fire hazard when used in the presence of volatile or flammable mixtures.

Fire Extinguishing Media: Water spray. Carbon Dioxide, Dry Chemical Powder or Appropriate Foam. Note: Use extinguishing media appropriate for surrounding fire.
Special Information: Firefighters should wear proper protective equipment and self-contained breathing apparatus with full facepiece operated in a positive pressure mode to prevent inhalation and contact with skin and eyes. Move exposed containers from fire area if it can be done without risk. Use water to keep fire-exposed containers cool.

6. Accidental Release Measures

Wear suitable clothing including respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Carefully sweep up and containerize for reclamation or disposal. Use non-sparking tools. Avoid raising dust. Vacuuming or wet sweeping may be used to avoid dust dispersal. Ventilate area and wash spill site and clean-up tools after material pickup is complete.

7. Handling and Storage

Keep away from heat, sparks and open flame. Avoid generating dust. Prevent formation of static electricity. Keep container tightly closed, stored in a cool dry ventilated area. Protect against physical damage. Suitable for any general chemical storage area. Containers of this material may be hazardous when empty since they retain product residues (dust, solids). Observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits: OSHA Permissible Exposure Limit (PEL): 15 mg/m3 (TWA) PEL is for Nuisance dusts and particulates. ACGIH Threshold Limit Value (TLV): 10 mg/m3 (TWA). This substance is listed as an ACGIH nuisance particulate. TLV listed is for nuisance dusts and particulates.
Ventilation System: A system of local and/or general exhaust is required to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.
Personal Respirators (NIOSH Approved): Do not breathe dust. If the exposure limit is exceeded, a half-face dust/mist respirator or mask may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest. A full-face piece dust/mist respirator may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency, or respirator supplier, whichever is lowest. For emergencies or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.
Skin Protection: Avoid contact with skin and clothing as a good industrial practice. Avoid prolonged or repeated exposure. Wear protective chemical-resistant gloves, safety goggles, and clean body-covering clothing. Wash thoroughly after handling. Safety shower and eye bath.
Eye Protection: Avoid contact with eyes. Use chemical safety goggles and/or full face shield where dusting or splashing of solutions is possible. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Form/Appearance: Low bulk density powder.
Color: Light colored whitish-yellow.
Odor: Slight citrus.
Solubility in Water: Both soluble and insoluble depending on phytochemical.
pH: Neutral (4.0 to 5.0)
Flash Point: No data available.
Flammability: Burns readily.

Auto Flammability: No data available.
Explosive Property: Dust is capable of creating a dust explosion.

10. Stability and Reactivity

Stability: Stable under ordinary conditions of use and storage.
Hazardous Combustion or Decomposition Products: Carbon monoxide, carbon dioxide.
Hazardous Polymerization: Will not occur.
Incompatibilities: None known.
Conditions to Avoid: Heat, flame and other sources of ignition. Formation of static electricity.

11. Toxicological Information

Eye: May cause eye, mouth and respiratory system irritation and dryness. No data available.
Skin: May cause skin irritation and dryness. No data available.
Inhalation: May cause respiratory system irritation. No data available.
Ingestion: May cause mouth irritation and dryness and dehydration if swallowed. No data available.
Carcinogenity: No evidence of carcinogenity.
Mutagenicity: No data available.
Teratogenicity: No data available.

12. Ecological Information

Environmental Fate: No data available.
Environmental Toxicity: No data available.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Hazard Class: Not classified.
Hazard Label: None required.

15. Regulatory Information

Hazard Class: Not required.

16. Other Information

Label Hazard Warning:
CAUTION! MAY CAUSE IRRITATION OF EYES, MOUTH, RESPIRATORY SYSTEM, DIGESTIVE SYSTEM AND SKIN.
Label Precautions: During use avoid contact with eyes, skin, clothing, inhalation or ingestion.
Label First Aid:
Eye Contact: Immediately flush with plenty of water for at least 15 minutes. Get medical advice if irritation develops.
Inhalation: Remove to fresh air. Get medical attention for any breathing difficulty.
Ingestion: If swallowed, wash mouth out with water and give several glasses of water to drink to dilute provided person is conscious. If large amounts were swallowed, get medical advice from a physician.

Skin Contact: Immediately wash skin with plenty of soap and water. Get medical advice if irritation develops.

Disclaimer: Fiberstar, Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. See invoice or packing slip, including reverse side, for additional terms and conditions of sale. FIBERSTAR, INC. MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, FIBERSTAR, INC. WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

Attachment C

FIBERSTAR®

Improving Food Freshness & Nutrition with Enhanced Natural Fiber™

Citri-Fi® 100 Technical Information

DESCRIPTION:	An all natural citrus fiber product to be used for fat replacement, moisture management, water and oil binding, or thickening.	
PROPERTIES	Physical form	Free flowing powder with >95% less than 30 mesh
	Color	Light yellow beige
	Carton Size	16" x 12" x 17" high
	Weight	42 pounds (19.0 kg)
	Cartons per pallet	40
LABEL DECLARATION	Bakery products: citrus fiber Meats products: dried orange pulp (or citrus flour)	
Non GMO	Citri-Fi® does not contain Genetically Modified Organisms (GMO).	
ALLERGEN STATEMENT	Product is derived from a non allergen source and presents essentially no allergenic risk to consumers.	
PACKAGING	Product should be stored in a clean, cool, dry place. This product will give full performance for a period of Thirty-six (36) months from date of manufacture. Each box contains a code that identifies the batch and date.	
REGULATORY STATEMENT	Citri-Fi® is manufactured under sanitary conditions in full compliance with the Federal Food, Drug and Cosmetic Act as amended, following current good manufacturing practices.	
ORIGIN	Product of the U.S.A.	

TYPICAL ANALYTICAL RESULTS FOR CITRI-FI® 100

Component	Results	Units
Calories (FBDG Subtracted)	226	Calories/100 g
Total Fat	1.05	%
Saturated Fat	0.31	%
Trans Fat	0.00	%
Monounsaturated fat	0.35	%
Cis-cis Polyunsaturated fat	0.39	%
Carbohydrates, Total	80.73	%
Fiber, Total Dietary	68.2	%
Soluble fiber	33.3	%
Insoluble fiber	34.9	%
Sugars	7.36	%
Protein by Dumas	8.15	%
Sodium	21.1	mg/100g
Moisture	7.42	%
Ash	2.65	%
Aerobic Plate Count	<10,000 CFU/g	
E. coli	<10	CFU/g
Listeria monocytogenes	Negative per 25 g	
Salmonella (Confirmed)	Negative per 25 g	

Attachment D

Evaluation Criteria for Substances Added to the National List

Category 1. Adverse impacts on humans or the environment?

Substance: **Dried Orange Pulp, Citri-Fi 100**

Documentation

1. Are there adverse effects on environment from manufacture, use or disposal? [§205.600 b.2]
   No.

2. Is there environmental contamination during manufacture, use, misuse or disposal? [§6518 m.3]
   No. Dried Orange Pulp is beneficial for the environment because it further processes a juice processing waste.

3. Is the substance harmful to the environment? [(1)(A)(i); 6517(c)(2)(A)i]
   No. Dried Orange Pulp is beneficial as it further processes a juice processing waste.

4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]
   No.

5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]
   No.

6. Are there adverse biological and chemical interactions in agroecosystem? [§6518 m.5]
   No.

7. Are there detrimental physiological effects on soil organisms, crops or livestock? [§6518 m.5]
   No.

8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]
   No.

9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]
   No.

10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c (2)(A)(i); §6518 m.4]
No.

11. Is there an adverse effect on human health as defined by applicable Federal regulations? [§205.600 b.3]
No. See Attached FDA GRAS – 000154.

12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]
Yes.

13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]
No.

Category 2. Is the substance essential for organic production?

Substance: **Dried Orange Pulp, Citri-Fi 100**

Documentation

1. Is the substance formulated or manufactured by a chemical process? [6502(21)]?
No.

2. Is the substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources? [6502(21)].
No.

3. Is the substance created by naturally occurring biological processes? [6502(21)]?
Yes. Dried orange pulp is an important use of a byproduct of orange juice processing.

4. Is there a natural source of the substance? [§205.600 b.1]
Dried Orange Pulp is prepared from a natural source, oranges.

5. Is there an organic substitute? [§205.600 b.1]
No. Dried Orange Pulp is a natural source and an organic substitute is not available.

6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]
Dried Orange Pulp has unique characteristics that are not available in organically produced agricultural products.

7. Is there a wholly natural substitute product? [§6517c(1)(A)(ii)]
Dried orange pulp is a wholly natural product.

8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]
Yes.

9. Is there any alternative substance(s)? [§6518 m.6]
No.

10. Is there another practice that would make the substance unnecessary? [§6518 m.6]
No.

Category 3. Is the substance compatible with organic production practices?

Substance: **Dried orange pulp, Citri-Fi 100**

Documentation

1. Is the substance compatible with organic handling? [§205.600 b.2]
Yes.

2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]
Yes. Because of the instability of the pulp created in orange juice processing, and the quantities required for efficient processing, it currently is not possible to use pulp created in processing of organic orange juice.

3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]
Yes. Dried orange pulp is an important environmental use of a byproduct of orange juice processing. The production of dried orange pulp adds economic value to this byproduct.

4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]
Yes.

5. Is the primary use as a preservative? [§205.600 b.4]
No.

6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing? [§205.600 b.4]
No.

7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:

   a. copper and sulfur compounds;
   b. toxins derived from bacteria;
   c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?
   d. livestock parasiticides and medicines?
   e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?

   No to all.