



Rayetta Henderson, Ph.D.
ToxStrategies, Inc.
1121 Military Cutoff Rd.
Suite C, Box 352
Wilmington, NC 28405

Re: GRAS Notice No. GRN 000884

Dear Dr. Henderson:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000884. We received the notice that you submitted on behalf of Florida Food Products, LLC (Florida Food) on September 25, 2019 and filed it on October 31, 2019. Florida Food submitted amendments to the notice on December 19, 2019, March 17, 2020, April 24, 2020, and May 5, 2020 that provided additional functionality data, information on dietary exposure to heavy metals, and clarifications regarding the intended use and the number of batch analyses. Florida Food submitted an amendment on February 3, 2020 that expanded the intended uses to include additional food categories while reducing the maximum use level.

The subject of the notice is rice bran extract for use as a moisture retention agent and an alternative to sodium phosphate at a maximum level of 1.25% by weight in meat and poultry, meat and poultry products, and processed meats, all of which are products under the jurisdiction of the U.S. Department of Agriculture (USDA). The notice informs us of Florida Food's view that these uses of rice bran extract are GRAS through scientific procedures.

Florida Food describes rice bran extract as a tan to brown water-soluble powder extracted from rice (*Oryza sativa*) bran. Florida Food states that the rice bran extract is composed of protein (7%), moisture (10%), carbohydrates (29%), dietary fiber (5%), total sugars (11%), ash (54%), total starch (6%), fat (<0.2%), phosphorus (5.5%), and sodium (18.6%).

Florida Food states that dehulled rice bran purchased from domestic rice milling companies is treated with dilute hydrochloric acid. This is followed by extraction with heat and agitation; the resulting liquid extract is centrifuged and filtered to remove insoluble solids and fine particulates. The filtered liquid extract is treated with an ion-exchange resin and sodium hydroxide and concentrated by vacuum evaporation. Florida Food states that the concentrated liquid extract is refrigerated, pasteurized and vacuum-dried prior to grinding to a fine powder. The powder is then treated with silicon dioxide (anticaking agent) and standardized with sea salt. Florida Food states that rice bran extract is manufactured in compliance with current good manufacturing practices with

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food-grade raw materials and processing aids.

Florida Food provides specifications for rice bran extract, including appearance, moisture ($\leq 12\%$), pH (5% solution; 6.0-8.0), total phosphorus (5-7%), total arsenic (< 1 ppm)¹, cadmium (< 0.4 ppm), lead (< 0.2 ppm), and limits on microorganisms and mycotoxins. Florida Food provides analytical results for three non-consecutive lots to demonstrate that rice bran extract meets specifications. Florida Food states that rice bran extract is stable at 24 °C for at least two years.

Florida Food provides an estimate of the dietary exposure to rice bran extract based on the intended uses. Florida Food obtained dietary survey data from What We Eat in America-Food Commodity Intake Database (WWEIA-FCID 2005-2010) and National Health and Nutrition Examination Survey (NHANES). Florida Food estimates the per-user mean and 90th percentile dietary exposures to rice bran extract to be 1.60 g/person (p)/day (d) and 3.00 g/p/d, respectively, for the U.S. population aged 2+ years. Florida Food calculates these to be 0.0247 g/kg body weight (bw)/d and 0.0467 g/kg bw/d, respectively, using the respondents' reported body weights that were not standardized to 60 kg. Florida Food states that the use of rice bran extract is self-limiting for technological reasons.

Florida Food estimates the mean and 90th percentile dietary exposures to total arsenic (including inorganic arsenic) from rice bran extract to be 0.89 and 1.71 $\mu\text{g}/\text{p}/\text{d}$, respectively. Florida Food states that this dietary exposure to total arsenic would be negligible and is not expected to contribute to background dietary exposure. Florida Food further notes that inorganic arsenic is water soluble and is expected to be removed during manufacturing.

Florida Food states that rice and its derivatives are widely used as a source of human food and rice has served as a staple for more than half the global population. Florida Food discusses several published safety studies for rice bran, rice bran extracts, and rice bran derivatives that include animal toxicology, pharmacokinetics, mutagenicity and human tolerance studies to demonstrate safety of its rice bran extract. No toxicologically relevant effects were reported by the authors under the conditions of these studies. Florida Food states that the composition of rice bran extract is similar to that of rice bran. Moreover, Florida Food states that rice is not a major allergen and the potential for rice bran extract to elicit an allergic response is low, given its composition and intended conditions of use.

Florida Food includes the report of a panel of individuals (Florida Food's GRAS panel). Based on its review, Florida Food's GRAS panel concluded that rice bran extract is safe under the conditions of its intended use.

¹ Florida Food analyzed three non-consecutive lots for all specifications, including total arsenic. FDA notes that the limit of quantitation of the method used to determine total arsenic (AOAC 993.14) is 10 ppb. Florida Food did not provide information regarding arsenic speciation. However, Florida Food notes that inorganic arsenic makes up a small percentage of total arsenic in rice, and that inorganic arsenic is water soluble, rendering its removal during the manufacture of rice bran extract.

Based on the totality of the data and information presented in its GRAS notice, Florida Food concludes that rice bran extract is GRAS under its intended conditions of use.

Use in Products under USDA Jurisdiction

As provided under 21 CFR 170.270, during our evaluation of GRN 000884, we coordinated with the Food Safety and Inspection Service (FSIS) of the USDA. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, FSIS determines the efficacy and suitability of ingredients used in meat, poultry, and egg products, and prescribes safe conditions of use. Suitability relates to the ingredient's effectiveness in performing its intended technical effect and the assurance that the ingredient's use will not result in products that are adulterated or misleading for consumers.

FSIS has advised the following with respect to the statutes it administers:

FSIS has completed its review and has no objection to the use of rice bran extract as a moisture retention agent and an alternative to sodium phosphate, at levels of up to 1.2% of the product formulation in meat and poultry products where the standards of identity permit such use.

Regarding labeling, Florida Food is required to label the ingredient as "rice bran extract" in the ingredients statement of the products in which it is used. Please contact Ms. Rosalyn Murphy-Jenkins at (301) 504-0879 or via email at Rosalyn.Murphy-Jenkins@usda.gov if you have questions regarding labeling.

FSIS requested that we advise you to seek regulatory guidance from its Risk Management and Innovations Staff (RMIS) about the use of rice bran extract in meat, poultry, and egg products. You should direct such an inquiry to Dr. Melvin Carter, Director, RMIS, Office of Policy and Program Development, FSIS by email at Melvin.Carter@fsis.usda.gov.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of Florida Food's notice concluding that rice bran extract is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing rice bran extract. Accordingly, our response should not be construed to be a statement that foods containing rice bran extract, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Florida Food provided, as well as other information available to FDA, we have no questions at this time regarding Florida Food's conclusion that rice bran extract is GRAS under its intended conditions of use. This letter is not an affirmation that rice bran extract is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 000884 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.

Carlson -S

Digitally signed by
Susan J. Carlson -S
Date: 2020.08.19
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Susan Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition

cc: Melvin Carter, Ph.D.

Director

USDA/FSIS/OPPD/RMIS

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