Donald Schmitt, MPH
Senior Managing Scientist
ToxStrategies, Inc.
931 W. 75th St., Suite 137, PMB 263
Naperville, IL 50650

Re: GRAS Notice No. GRN 000720

Dear Mr. Schmitt:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000720. We received the notice that you submitted on behalf of J.M. Smucker Co. (Smucker) on July 17, 2017, and filed it on August 9, 2017.

The subject of the notice is rice bran wax. The notice informs FDA of the view of Smucker that rice bran wax is GRAS through scientific procedures, for use as a texturing agent in peanut butter used in bar products at levels up to 3%. Rice bran wax is regulated for use in 21 CFR 172.890.

Smucker provides information about the identity of rice bran wax, CAS No: 8016-60-2. Smucker describes rice bran wax, made from *Oryzae sativa* (rice) husks, as a hard, crystalline, non-hydrogenated wax that is yellow to light brown in color. Smucker states that 98% of rice bran wax consists of long-chain aliphatic monoesters that range from 48 to 64 carbons in length. Smucker notes that rice bran wax has a melting point of 75-86°C.

Smucker describes the method of manufacture for rice bran wax. The starting material, crude rice bran wax, is melted in a clean tank with physical separation of solid impurities. The melted wax is mixed with decoloring agents in another tank and then filtered until it is clear. The wax is further filtered, made into uniform pellets, packaged, and labeled. The notifier states that the manufacturing process is conducted in accordance with current good manufacturing practices.

Smucker provides specifications for rice bran wax, which include limits for heavy metals (arsenic ≤0.2 mg/kg, cadmium ≤0.4 mg/kg, lead ≤0.2 mg/kg, and mercury ≤0.1 mg/kg) and microbial contaminants. Smucker provides the results of three non-consecutive

batch analyses of rice bran wax to demonstrate that it meets these specifications. Smucker states that the use of rice bran wax in foods is considered self-limiting for technological reasons, such as product texture and/or flavor profile, either of which could affect consumer acceptability.

Smucker discusses the dietary exposure to rice bran wax from proposed and currently regulated uses. Smucker includes exposure estimates to rice bran wax from the 2009-2010 and 2011-2012 food consumption surveys reported in the "What We Eat in America" (WWEIA) portion of the National Health and Nutrition Examination Survey. The dietary exposures to rice bran wax for the U.S. population (above the age of 2) are 800 mg/person/day (mg/p/d) at the mean and 1300 mg/p/d at the 90th percentile (10 and 30 mg/kg body weight (bw)/d). For 2-5 year-old children, the dietary exposures to rice bran wax are 600 mg/p/d at the mean and 1200 mg/p/d at the 90th percentile (40 and 80 mg/kg bw/d). Smucker notes that two-day survey data from WWEIA are likely to significantly overestimate the actual consumption frequency of bar products since only 6-7% of the population reported consuming these bars over the two survey days.

Smucker also discusses an analysis conducted by FDA using 10-14 day dietary recall data from the NPD Group Inc.'s National Eating Trends-Nutrient Intake Database (NPD NET-NID)[1]. The dietary exposures to rice bran wax for the U.S. population (above the age of 2) are 100 mg/p/d at the mean and 200 mg/p/d at the 90th percentile (3 and 5 mg/kg bw/d). For 2-5 year-old children, the dietary exposures to rice bran wax are 100 mg/p/d at the mean and 200 mg/p/d at the 90th percentile (7 and 14 mg/kg bw/d). Smucker notes that the significantly lower estimates of average daily exposure to rice bran wax that are based on data from longer term survey data (NPD NET-NID) are a result of the consumption of the bars being infrequently reported, and are more realistic estimates of chronic exposure than those from the method discussed above.

Smucker discusses the safety of rice bran wax, noting an updated search of the literature through June 2017. Smucker states that while other waxes, such as carnauba wax, candelilla wax, beeswax, and lanolin wax contain lesser amounts of long-chain aliphatic monoesters, the safety information for those waxes can also be considered for the safety conclusion of rice bran wax. Smucker states that monoesters in rice bran wax and other similar waxes are generally not absorbed, and when absorption does occur, the esters are hydrolyzed and metabolized into their corresponding fatty acids and alcohols, which are further metabolized through normal cellular metabolic pathways.

Smucker discusses published and unpublished studies in rodents and dogs to assess the safety of rice bran wax. These include published subchronic repeat-dose toxicity studies on carnauba wax, jojoba oil, and oleyl palmitate ranging from 4 days to 28 weeks. Smucker also discusses a published reproductive toxicity study in rats with carnauba wax, the same study evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to determine a no observed adverse effect level of 670 mg/kg bw/d and an acceptable daily intake of 0-7 mg/kg bw/d for carnauba wax. As corroborative evidence for safety, Smucker also discusses unpublished studies in rodents and dogs on carnauba wax, candelilla wax, and jojoba wax/oil, which were also reviewed by the

[1] A dietary exposure estimate to rice bran wax from the proposed uses is provided in a memorandum by R. Shah dated April 20, 2017.

European Food Safety Authority (EFSA) and/or JECFA. Smucker states that EFSA and JECFA evaluations of published and unpublished toxicity studies reveal no toxicologically relevant adverse effects from exposure to waxes, similar to rice bran wax. Smucker also states that rice bran wax and related waxes are neither genotoxic nor mutagenic based on a published mutagenicity study on candelilla wax and beeswax and supported by unpublished mutagenesis and genotoxicity studies on rice bran, carnauba, and candelilla waxes.

Smucker includes the report of a panel of individuals (Smucker's GRAS panel). Based on its review, Smucker's GRAS panel concludes that rice bran wax is safe under the conditions of its intended use.

Based on the data and information described above, Smucker concludes that rice bran wax is GRAS for its intended use in food.

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 its review of Smucker's notice that rice bran wax is GRAS for the intended use, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing rice bran wax. Accordingly, this response should not be construed to be a statement that foods that contain rice bran wax, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Smucker provided, as well as other information available to FDA, we have no questions at this time regarding Smucker's conclusion that rice bran wax is GRAS under its intended conditions of use. This letter is not an affirmation that rice bran wax 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 000720 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Michael A. Adams -S

Digitally signed by Michael A. Adams -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300042713, cn=Michael A. Adams -S
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