November 5, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned submits this petition on behalf of the Alliance of African Shea Associations (AASA) under Section 401 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 341, to request that the Commissioner of Food and Drugs amend the standards of identity for chocolate (21 C.F.R. §§ 163.123, 163.124, and 163.130) to provide for the optional use of shea-based ingredients as alternatives to cacao fat.

AASA represents several national organizations in West Africa, which have common goals related to the promotion of profitable, socially equitable, and environmentally sustainable production and trade of shea products. Shea trees (*Vitellaria paradoxa*) are native to a band of countries at the northern part of sub-Saharan Africa, which includes part of West, Central, and East Africa. Throughout this band, sheanuts are picked and processed primarily by women for use in a variety of food, cosmetic, and pharmaceutical products.

Oil extracted from sheanut kernels in this region has been consumed locally, for cooking and as an ingredient in cosmetics, traditional soaps, and other products. International demand for shea products has developed over time, leading to increased economic opportunities for the African women who collect sheanuts, but also a need for greater coordination to address local, regional, and international barriers to such opportunities. AASA is an alliance of several national organizations that have formed to meet this need. AASA includes the Shea Network of Ghana, National Shea Products Association of Nigeria, Table Filière Karité of Burkina Faso, and Fédération Nationale de Karité of Mali. AASA also represents organizations that are forming in Benin and Côte d'Ivoire.

AASA submits this petition to address a significant barrier to economic opportunity currently imposed by the standards of identity for chocolate. Currently, shea exports from West Africa may be used in chocolate products sold in the European Union (EU) and other jurisdictions that permit alternatives to cacao fat in chocolate, including alternatives derived from combinations of sheanut oil and palm oil. See, e.g., Directive 2000/36/EC of the European Parliament and of the Council art. 2 (June 23, 2000) (Attachment 1). But, because the current standards of identity prohibit use of any alternatives to cacao fat in products labeled as "chocolate," they prevent similar access to the United States market. Amendment of the standards would remove this barrier.

I. Action Requested

This petition requests that the Commissioner of Food and Drugs amend the standards of identity for sweet chocolate (21 C.F.R. § 163.123), white chocolate (§ 163.124), and milk chocolate (§ 163.130) to provide for the optional use of shea-based ingredients as

alternatives to cacao fat. The amended regulations would specifically provide for optional use of certain combinations of sheanut oil and palm oil fractions. When used in chocolate, such combinations are equivalent to cacao fat in all material respects, as explained in detail below.[1]

The proposed text of the amended regulations is provided in Appendix I. In summary, the list of optional ingredients for each regulation would be amended to include the following:

Any blend of palm oil and sheanut oil that is:

(i) Miscible in any proportion with cacao fat and compatible with its physical properties (melting point and crystallization temperature, melting rate, and need for tempering phase); and

(ii) Obtained by the processes of refining and fractionation, which excludes enzymatic modification of triglyceride structure.

The general description for each regulation would also be amended to provide that finished chocolate must contain not more than 5 percent by weight of any blend or blends of sheanut oil and palm oil fractions.

II. Statement of Grounds

The purpose of the proposed amendment is to allow for use of safe and suitable shea-based alternatives to cacao fat in the production of chocolate. The amendment would fully preserve the basic nature and essential characteristics of chocolate, but also provide sheanut collectors in West Africa with an important opportunity for access to the United States market.[2]

This proposal is premised on the fact that the compositional characteristics and physical properties of cacao fat are largely responsible for the basic nature and essential characteristics of chocolate. As explained in detail below, the shea-based alternatives to cacao fat at issue here have the same triglycerides and the same physical properties as cacao fat and can therefore be used as cacao fat alternatives without affecting the basic nature or essential characteristics of chocolate. The amendment would also be consistent with FDA's initiative to modernize the food standards and would align FDA's regulations with the relevant standards in the EU and other jurisdictions. See 60 Fed. Reg. 67492 (Dec. 29, 1995); 70 Fed. Reg. 29214 (May 20, 2005).

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[1] FDA has already determined that sheanut oil is generally recognized as safe (GRAS) when used under the conditions prescribed in 21 C.F.R. § 184.1702. These conditions include use in chocolate products. See id. § 184.1702(c).

[2] Although FDA regulations currently permit limited use of vegetable fats in some chocolate-based products, these must generally be labeled as vegetable fat coatings. See 21 C.F.R. §§ 163.150, 163.153 & 163.155. As a result, the regulations do not currently provide a commercially viable route to marketing of shea-based chocolate products.

A. Background

FDA has recognized that the principal characteristics of sweet and milk chocolate include their "chocolate taste, flavor, aroma, and color," which are derived from the ingredient chocolate liquor. Milk chocolate is further characterized by "its readily perceptible taste and flavor of milk and other characteristics resulting from the quantity of milk solids used." 9 Fed. Reg. 14329, 14331, 14333 (Dec. 6, 1944).

White chocolate does not have the same characteristic chocolate flavor—because it does not contain chocolate liquor—but FDA has nonetheless recognized that consumers generally expect a white chocolate product to contain certain cacao-derived ingredients because the term "chocolate" is used in the name. 67 Fed. Reg. 62171, 62173-74 (Oct. 4, 2002).

Overall, the current standards ensure that chocolate products have the expected taste, flavor, aroma, color, and cacao-derived ingredients, by establishing the following:

- minimum amounts for chocolate liquor in sweet and milk chocolate;
- a maximum amount for milk solids in sweet chocolate;
- minimum amounts for milkfat and milk solids in milk and white chocolate; and
- a minimum amount of cacao fat in white chocolate.

21 C.F.R. §§ 163.123(a)(2), 163.124(a)(2), 163.130(a)(2).

FDA has recognized that key characteristics of chocolate also include its unique "plasticity" or "viscosity." See 9 Fed. Reg. at 14332. These characteristics include an attractive "snap" (the clean fracture that occurs when a chocolate bar is broken with the hands) and appropriate melting behavior (solid at room temperature, but able to melt pleasantly in the mouth). These characteristics are related to several physical properties of cacao fat—including its melting and crystallization characteristics.[3]

These physical properties are due to the triglyceride composition of cacao fat.[4] Cacao fat primarily consists of symmetrical, "SUS-type" triglycerides, which are composed of two saturated fatty acids (S) in the outside positions and one unsaturated fatty acid (U) in the central position. The SUS-type triglycerides in cacao fat include:

- POP, consisting of palmitic acid (P) in the outside positions and oleic acid (O) in the central position;
- POSt, consisting of palmitic acid (P) in one outside position, oleic acid (O) in the central position, and stearic acid (St) in the other outside position; and

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[3] M. Lipp & E. Anklam, Review of Cocoa Butter and Alternative Fats for Use in Chocolate—Part A. Compositional Data, Food Chemistry, 62(1):73, at 74-75 (1998) (Attachment 2).

[4] Geoff Talbot & Hennie Slager, Cocoa Butter Equivalents and Improvers: Their Use in Chocolate and Chocolate-Coated Confectionery, AgroFOOD Industry Hi-Tech 19(3):28, at 28 (2008 supplement) (Attachment 3); Lipp & Anklam, supra note 3, at 75.

- StOSt, consisting of stearic acid (St) in the outside positions and oleic acid (O) in the central position.

The comparative levels of these triglycerides in cacao fat are highest for POSt and lowest for POP. The total amount of all three triglycerides is generally above 70%.[5]

Certain other ingredients contain the same SUS-type triglycerides as cacao fat, such as the sheanut oil and palm oil that are the subject of this petition. Individually, each of these two oils contain POP, POSt, and StOSt in proportions that are different from cacao fat. But, they can be blended in a manner that results in a single ingredient with a triglyceride composition that has characteristics comparable to those of cacao fat. Additionally, blends can be made with triglyceride compositions that have improved physical properties compared to cacao fat and that can be used to make corrections for seasonal and geographical variations that affect the quality of cacao fat, as described below.[6]

In recognition of this, substitution of cacao fat with shea-based ingredients has already been permitted in chocolate products sold in the EU since 2000. See Directive 2000/36/EC, at art. 2. The addition of such fats to chocolate and chocolate products has also been permitted under the *Codex Alimentarius* since 2003. See Codex Standard for Chocolate and Chocolate Products (Codex Stan. 87-1981) § 2 (rev. 1-2003) (Attachment 6). Other countries also allow for the use of alternatives to cacao fat, including Australia, New Zealand, and Singapore. See Australia New Zealand Food Standards Code, Standard 1.1.2 (Attachment 7); Singapore Food Regulations § 168 (Attachment 8).

This proposal is based on the pre-existing EU and Codex standards and would ensure that cacao fat will be substituted only with fats that have the same triglycerides and physical properties as cacao fat. This would ensure that any such substitution will result in chocolate products with the same basic nature and essential characteristics as those currently produced under the existing FDA standards of identity.

B. Amended Standards Would Preserve the Basic Nature and Essential Characteristics of Chocolate

The overarching purpose of any food standard is to promote honesty and fair dealing in the interest of consumers. See 21 U.S.C. § 341; 21 C.F.R. § 130.5(b). This is achieved when consumer expectations of a particular food are met, considering factors such as the basic nature and essential characteristics of the food. See 70 Fed. Reg. 29214, 29221-22 (May 20, 2005).

This proposed amendment satisfies these requirements because it would result in no detectable change to the flavor profile or other sensory characteristics of chocolate products.

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[5] Ian Stewart & Jens Kristott, European Union Chocolate Directive Defines Vegetable Fats for Chocolate, Lipid Technology 16(1):11, at 13 table 2 (2004) (Attachment 4); Lipp & Anklam, supra note 3, at 77 table 5.

[6] See Talbot & Slager, supra note 4, at 28-29; Jari Alander, Shea Butter—A Multifunctional Ingredient for Food and Cosmetics, Lipid Technology 16(9):202, at 202-203 & table 1 (2004) (Attachment 5); Stewart & Kristott, supra note 5, at 12 tables 1-2, & 13; Lipp & Anklam, supra note 3, at 82 & 84.

As already noted, the existing chocolate standards ensure the characteristic taste, flavor, aroma, and color of sweet and milk chocolate by setting minimum and maximum amounts for chocolate liquor, milkfat, and milk solids. The existing standard for white chocolate also ensures that consumer expectations are met by prescribing a minimum amount of cacao fat.

The proposed amendment would not affect the taste, flavor, aroma, or color of chocolate because it would not alter any of these current minimums and maximums.[7] The proposed amendment would only allow for limited replacement of the additional cacao fat that is currently permitted as an optional ingredient. Cacao fat imparts little flavor to finished chocolate products and the blends that would be permitted under this amendment would themselves be flavorless. In addition, the blends would have the same triglycerides and physical properties as cacao fat, ensuring that chocolate made with the blends would also have all of the physical characteristics that consumers currently expect. Products made with the blends would be brittle at room temperature and melt at body temperature, just like products made only with cacao fat.[8]

C. The Proposed Amendment Is Consistent with FDA Efforts to Permit Flexibility

FDA recognizes that food standards should permit flexibility in food technology, so long as that technology does not adversely affect the basic nature, essential characteristics, nutritional quality, or safety of a food. 70 Fed. Reg. at 29222. Further, the agency has recognized that food standards may serve as an "impediment" to the food industry when "they fail to reflect advances in food science and technology." 60 Fed. Reg. 67492, 67499 (Dec. 29, 1995).

The proposed amendment would provide for an appropriate level of flexibility in chocolate production because shea-based ingredients can be used to achieve consistency and efficiency in the production process and to make better quality products. For example, there is natural variability in cacao fat composition from season to season, year to year, and region to region. This natural variability can cause variations in hardness and heat resistance. Shea-based blends can be customized to balance out this variability and achieve consistent quality in the ingredients used to make chocolate. Customized blends can also be used to optimize characteristics of the chocolate itself, such as tempering behavior, hardness, and resistance to heat and "bloom" (a whitish coating that can appear on the surface of chocolate).[9]

As already discussed, the amendment would permit this flexibility without adversely affecting the basic nature or essential characteristics of chocolate, largely because the shea-based ingredients would have the same triglycerides and physical properties as the cacao fat they replace. There would also be no adverse impact on the nutritional quality of chocolate for the same reason. Specifically, there would be little or no change to the total fat

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[7] See Eva Vitova, Blanca Loupancova, Hana Stoudkova, Ivana Macku, Jana Zemanova, and Libor Babak, Effect of Fat Composition on Some Physico-Chemical Parameters and Sensorial Evaluation of Dark Chocolate, J. Food & Nutrition Research 48(2):72, at 72-73 (2009) (Attachment 9).

[8] Alander, supra note 6, at 203; Stewart & Kristott, supra note 5, at 13; Lipp & Anklam, supra note 3, at 74-75, 84; see also Talbot & Slager, supra note 4, at 29 fig. 2 (showing very little change in melting profile of chocolate when up to 15% of cacao fat (cocoa butter) is replaced with a "cocoa butter equivalent" (CBE)).

[9] See Talbot & Slager, supra note 4, at 28-29; Stewart & Kristott, supra note 5, at 13.

content of chocolate, or to the corresponding carbohydrate, protein, and overall calorie content of chocolate. There would also be little or no change to saturated fat content because sheanut oil and palm mid-fraction contain comparable amounts of saturated fat, as compared to cacao fat.[10]

D. The Proposed Amendment Would Promote Harmonization of U.S. and International Food Standards

FDA recognizes that food standards should be "harmonized with international food standards to the extent feasible." 70 Fed. Reg. at 29223; see also 21 C.F.R. § 130.6(a) ("All food standards adopted by the Codex Alimentarius Commission will be reviewed by the Food and Drug Administration and will be accepted without change, accepted with change, or not accepted.").

As noted above, the shea-based equivalents to cacao fat are already permitted in Australia, New Zealand, Singapore, and the EU, and they are already permitted under the *Codex Alimentarius*. Products with such ingredients have been successfully marketed. For example, three leading brands of milk chocolate in the United Kingdom all contain both "cocoa butter" and "vegetable fat," in conformity with the EU directive. (See Attachment 10 (labeling for recently purchased bars of Dairy Milk, Galaxy, and Yorkie).)

This proposal is largely based on the EU and *Codex* standards. Like the relevant EU standard, this proposal provides for use of ingredients that are obtained only by the processes of refining and fractionation, and limits its usage to 5 percent of the finished product by weight. The proposal also reflects all of the relevant limitations of the EU standard needed to ensure that only appropriate equivalents for cacao fat are used: sheanut oil and palm oil are both non-lauric fats that are rich in symmetrical SUS-type triglycerides, and the proposal expressly requires that any blend used in chocolate be miscible in any proportion with cacao fat and compatible with its physical properties. See Directive 2000/36/EC, at art. 2(1) & annex II; see also Codex Alimentarius § 2 ("The addition of vegetable fats other than cocoa butter shall not exceed 5% of the finished product . . . .").

In addition, a refusal by FDA to revise the current food standards for chocolate would be inconsistent with the United States' international legal obligations to all of the West African nations affected by this proposal. As a Member of the World Trade Organization (WTO), the United States is obligated to ensure that its technical regulations and standards do not erect unnecessary barriers to trade. This obligation arises out of the WTO Agreement on Technical Barriers to Trade (the TBT Agreement). See Uruguay Round Agreements Act § 101(d)(5) (codified at 19 U.S.C. § 3511(d)(5) (Congressional approval and entry into force of TBT Agreement)); http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf.

The current standards for chocolate in the United States must be changed because they constitute impermissible barriers to trade under the TBT Agreement. The current standards create an unnecessary obstacle to international trade, and there are less trade-restrictive ways of accomplishing the United States' objective of maintaining the principal characteristics of chocolate in products labeled and sold as "chocolate." See TBT Agreement, art. 2.2. The current standards also deviate from existing international standards (i.e., those set by the *Codex Alimentarius*) without a legitimate justification. See TBT Agreement, art. 2.4. For

[10] Lipp & Anklam, supra note 3, at 76 table 4, 78 table 7 & 82 table 13.

both of these reasons, maintenance of the current standards is a potential violation of the United States' international obligations.

III. Environmental Impact

The action requested by the petition is not expected to have a significant effect on the quality of the human environment and is subject to categorical exclusion under 21 C.F.R. § 25.32(a).

IV. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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For questions regarding this petition, please contact pro bono counsel for AASA:

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Respectfully submitted,

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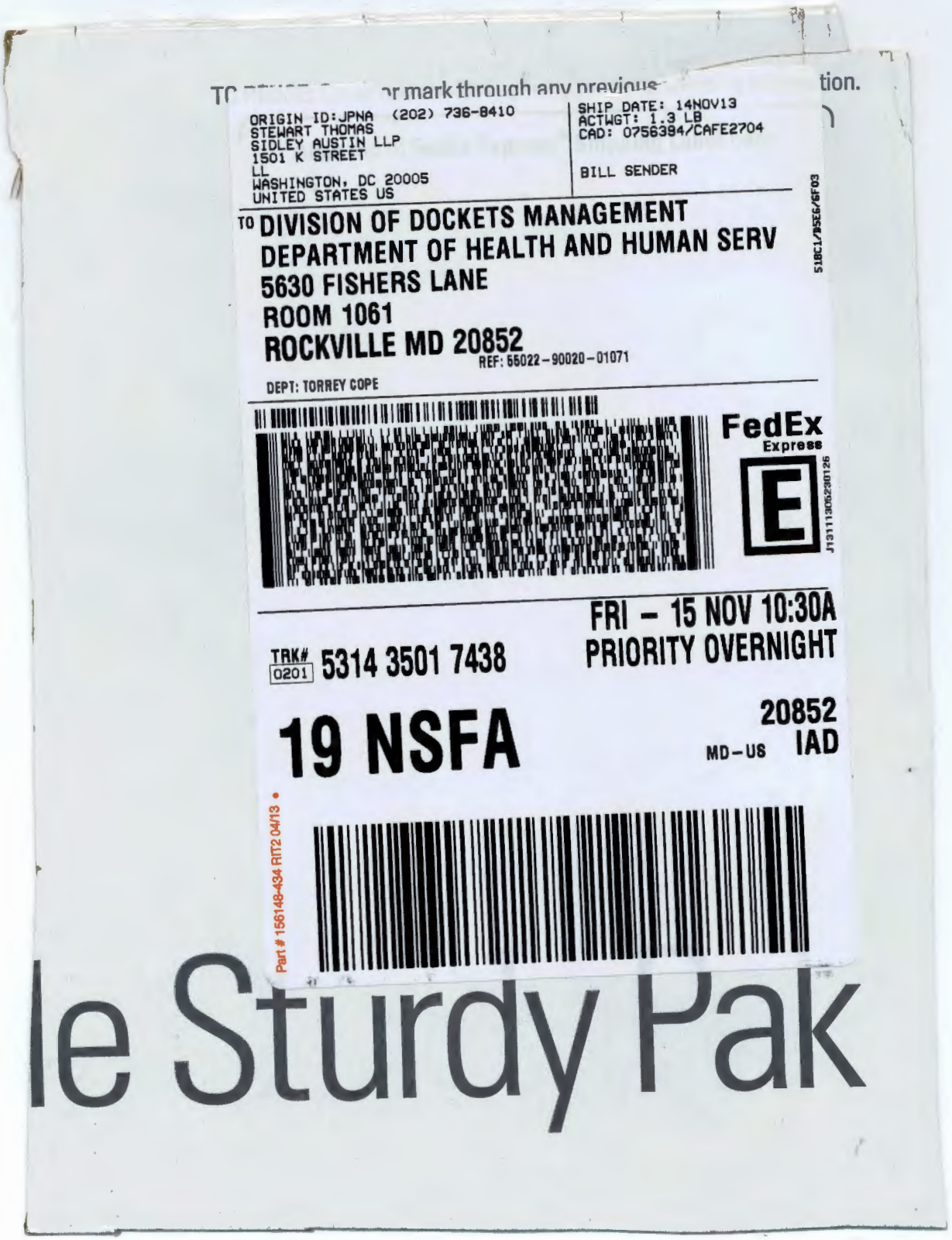
Enclosures: Proposed Text of Amended Chocolate Standards
List of Attached References
References (10)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