



JUN 16 2008

Cheryl Deem
Executive Director
American Spice Trade Association, Inc.
2025 M Street, NW
Suite 800
Washington, DC 20036

Dear Ms. Deem:

This is in response to your letter dated January 7, 2008, to the Food and Drug Administration (FDA) regarding the appropriate labeling of paprika and paprika products and foods containing these products. You noted that your current submission reflects the issues discussed at your meetings with FDA on January 12 and June 21, 2007. You provided information on the description, use, and relevant industry practice related to ground paprika, defatted paprika, paprika oleoresin, and paprika containing defatted paprika. In addition, in light of existing relevant FDA regulations and prior FDA opinion provided to manufacturers, you proposed appropriate labeling of these products when marketed as finished foods as well as when used as ingredients in other finished foods and asked the agency to provide its view on your conclusions.

We thank you for the information you provided and for your review of FDA regulations and prior FDA opinion related to this matter. We have considered all information available to us, including existing FDA regulations, compliance policy guides, and previous agency advice to manufacturers on the labeling of paprika and paprika-related products. Based on our review, we clarify below the appropriate labeling of each of the paprika products you mentioned in your submission.

A. Labeling of Paprika

In the absence of a definition or standard of identity for spices, in CPG 7109.20, FDA provided descriptions of spices, including paprika, as guidance concerning acceptable names for use in labeling of commonly used spices (Sec. 525.750, Spices – Definitions, FDA/ORA Compliance Policy Guides Manual). Paragraph 25 of this CPG describes paprika as “the sweet, non-pungent, or, if specified, slightly pungent, dried, ground, red, ripe fruit of *Capsicum annum* L.” FDA established a color additive regulation governing the use and labeling of paprika as a color in foods (21 CFR 73.340 and, by cross reference, 21 CFR 70.25). Paprika is also recognized in FDA regulations for its function as a spice in foods (21 CFR 182.10), the labeling of which is specified in 21 CFR 101.22. The labeling of paprika, when marketed as the finished food and when used as a color or spice ingredient in another finished food, must be in compliance with these regulations. We have summarized below the appropriate labeling in each case. However, note that labeling of these products must comply with all other requirements as specified in the above-mentioned and other applicable regulations.

When paprika is marketed as the finished food, the appropriate labeling is:

Name – “paprika” (the term “ground” may be used, as appropriate)

Ingredient statement – Not required provided paprika has no other added ingredients. However, if paprika has any added ingredient(s), each of the ingredients must be declared in accordance with 21 CFR 101.4.

Note that labeling must comply with all other applicable requirements (for example, when sold as a color additive, labeling must comply with §§ 73.340 and 70.25).

We agree with your conclusion that descriptors such as “100% paprika” or “pure paprika” may be used in the labeling of ground paprika that does not contain any diluents or other ingredients, except permitted functional ingredients such as anti-caking agents. Note that terms such as “pure” are not a part of the name of the food and, if used, must be presented in a manner that is truthful and not misleading.

When paprika is used as a spice in another finished food, the appropriate labeling is:

Ingredient statement of the finished food – “paprika” or “spice and coloring.” Any additional ingredients of the paprika must be declared unless exempt from declaration under the provisions of §§ 101.22(h)(2) and 101.100(a)(3).

When paprika is used as a color additive in another finished food, the appropriate labeling is:

Ingredient statement of the finished food – “colored with paprika,” “paprika color,” “color added,” “artificial color” or “artificial color added” (or an equally informative term that makes clear that a color additive has been used in the food), in accordance with § 101.22(k)(2).

B. Labeling of Paprika Oleoresin

Paprika oleoresin is a color additive described in 21 CFR 73.345 and permitted for use as color in foods. The color additive paprika oleoresin is defined as the combination of flavor and color principles obtained from paprika (*Capsicum annum* L.) by extraction, using one or more of the solvents specified in that regulation. The labeling of paprika oleoresin when it is the finished food or when it is used as a color in another finished food must be in accordance with §§ 73.345, 70.25, and 101.22(k) and is summarized below. However, note that the labeling of these foods must comply with all other requirements as specified in the above-mentioned and other applicable regulations.

When paprika oleoresin is marketed as the finished food, the appropriate labeling is:

Name: "paprika oleoresin"

Ingredient statement – Not required provided paprika oleoresin has no other added ingredients. However, if paprika oleoresin has any added ingredient(s), each of the ingredients must be listed in the ingredient statement in accordance with §§ 101.4 and 70.25.

When paprika oleoresin is used as a color additive in another finished food, the appropriate labeling is:

Ingredient statement of the finished food – "colored with paprika oleoresin," "paprika oleoresin color," "color added," "artificial color" or "artificial color added" (or an equally informative term that makes clear that a color additive has been used in the food), in accordance with § 101.22(k)(2).

C. Labeling of Defatted Paprika

FDA did not establish a definition or regulations for the use or labeling of a product named "defatted paprika." However, it has previously advised industry that the agency would not object to the use of the term "defatted paprika" or "defatted paprika meal" for shredded or ground paprika that is washed with hexane to remove all of its color and flavor components and subsequently treated to remove the residual solvent. The difference between ground paprika and the hexane-washed paprika meal is that the fat is removed (Letter to Dr. Winston Boyd from FDA, dated September 15, 1997). It is our understanding, as noted in your submission, that defatted paprika or defatted paprika meal is used as a diluent to standardize the color of ground paprika (Letter to Mr. Richard Wood from FDA, dated May 8, 1998). We have no information that suggests that "defatted paprika" or "defatted paprika meal" is not an appropriate name for a paprika product produced in the manner described above. Therefore, we reiterate that ground paprika that is treated (with hexane and within applicable conditions of safe use specified in FDA regulations) to remove all of its color and flavor components and subsequently treated to remove the residual solvent can be named "defatted paprika" or "defatted paprika meal." This defatted paprika must be declared as such in the ingredient statement of a finished food in which it is used as an ingredient.

D. Labeling of Paprika Containing Defatted Paprika

We have previously advised manufacturers on the labeling of paprika products that are not simply ground paprika, paprika oleoresin, or defatted paprika. Such products include 1) paprika containing defatted paprika or paprika meal and 2) paprika that is treated to standardize the color or flavor/aroma of paprika such that the color or flavor components are partially (not completely) removed and where the resulting product is comparable in color and flavor to commercially available "paprika."

In your submission, you asked for our views with respect to the labeling of paprika containing defatted paprika. You stated that such paprika containing defatted paprika should not use the descriptors "paprika," "100% paprika," or "pure paprika." Rather, you proposed that an appropriate name of such a product is "paprika with defatted paprika." In addition, you stated that paprika containing defatted paprika is most likely to be used to impart color to foods. Therefore, when used as a color ingredient in a finished food, you proposed that it is appropriate to list this paprika product in the ingredient statement of the finished food as "colored with paprika," "artificially colored," or "color added."

We agree with your conclusion that paprika containing defatted paprika cannot be named simply "paprika." Descriptors such as "100% paprika" or "pure paprika" in the labeling of paprika containing defatted paprika would be misleading in that these descriptors imply that the product consists of ground paprika only. We also agree that an appropriate name for such paprika product is "paprika with defatted paprika," with each of the ingredients declared in the ingredient statement of the paprika product.

When paprika containing defatted paprika is used specifically for its function as a color in another food, we believe that an appropriate declaration in the ingredient statement of the finished food is "artificial color," "artificial color added," or "color added," in accordance with § 101.22(k)(2). When added to foods as a color, paprika containing defatted paprika fits within the description of "artificial color" or "artificial coloring" (see § 101.22(a)(4) and, by cross reference, § 70.3(f)). In addition, based on the information in your submission, we would not object to your proposed declaration of this color ingredient as "colored with paprika" or "artificially colored" in the ingredient statement of the finished food.

When paprika containing defatted paprika is marketed as the finished food, the appropriate labeling is:

Name – "paprika with defatted paprika"

Ingredient statement – "paprika, defatted paprika." If the paprika product has any other ingredient(s), each of the ingredient(s) must be declared in accordance with § 101.4.

Note that labeling must comply with all other requirements in applicable regulations. Use of descriptors such as "100% paprika" or "pure paprika" is not appropriate in the labeling of this product.

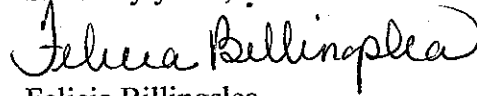
When paprika containing defatted paprika is used as a color in another finished food, the appropriate labeling is:

Ingredient statement of the finished food – “artificial color,” “artificial color added,” or “color added” (or an equally informative term that makes clear that a color additive has been used in the food), in accordance with § 101.22(k)(2).

We would not object to your proposed declaration as “colored with paprika” or “artificially colored.”

We hope the above provides the clarification you requested. Should you have additional questions, do not hesitate to contact us.

Sincerely yours,



Felicia Billingslea

Director

Food Labeling and Standards Staff

Office of Nutrition, Labeling,

and Dietary Supplements

Center for Food Safety

and Applied Nutrition