



DEC 3 2001

5301 '01 DEC -7 A9:25

Ms. Fran Stevens
7661 S. Avenida de Pina
Tucson, Arizona 85747

Docket No. 99P-2148/CP 1

Dear Ms. Stevens:

This is in response to your citizen petition, filed June 28, 1999, requesting that the Food and Drug Administration (FDA) amend food labeling regulations 21 CFR 101.4 and 101.22 to require declaration of the source of certain ingredients and to require the specific ingredient listing of spices and natural and artificial flavors on the label. In your petition, you stated that your daughter has a life threatening peanut allergy, which makes it difficult for your family to purchase manufactured food.

We understand your concern regarding your daughter's allergy to peanuts. FDA, as well, is concerned about informing consumers about allergenic substances in food.

We would like to point out that on May 30, 2000, we received another citizen petition (docket number 00P-1322/CP 1) that addressed allergens. This petition from the Attorneys General of New York, Maryland, Michigan, Wyoming, Ohio, Tennessee, Connecticut, Vermont, and Massachusetts specifically requested, among other things, that any flavoring be declared by its common or usual name, and that manufacturers adopt Good Manufacturing Practices to prevent cross-contact with allergenic substances. Petition 00P-1322/CP 1 raises concerns similar to those raised in your petition, and it provides data and specific legal arguments that you did not provide in your petition. Therefore, in accordance with 21 CFR 10.30(e)(3), this letter is to advise you of the action that FDA is taking on your petition. We are closing your petition and converting it to a comment to citizen petition 00P-1322/CP 1. Please be assured that we will consider the issues raised in your petition before making a final decision on this issue.

Sincerely yours,

Christine Lewis Taylor, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

99P-2148

ANS 2

Feel free to print out and distribute to friends, support groups, health food stores, and allergists. Once completed, send to the FDA at: Dockets Management Branch, HFA-305; Food and Drug Administration; 5630 Fishers Lane, Rm 1061; Rockville, MD 20852

Please note that changes might be made to this petition, per FDA request. 1 P1:48

Citizen Petition

The undersigned submits this petition under Title 21 Food and Drug regulation 21CFR 101.4(a)(1) Food Designation of ingredients, and regulation 21CFR 101.22 (h)(1)(2) Spices and Natural flavors to request the commissioner of Food and Drugs to amend the above regulations.

A. Action requested

Regulation 21CFR 101.4(a)(1) Food Designation of ingredients, states: Sec. 101.4 Food designation of ingredients. Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by Sec. 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of Sec. 101.2

Regulation 21CFR 101.22(h)(1)(2) states: (h) The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way: (1) Spice, natural flavor, and artificial flavor may be declared as "spice", "natural flavor", or "artificial flavor", or any combination thereof, as the case may be. (2) An incidental additive in a food, originating in a spice or flavor used in the manufacture of the food, need not be declared in the statement of ingredients if it meets the requirements of Sec. 101.100(a)(3).

I, Jamie Stevens, suffer from food allergies, which makes it very difficult for my family and me to purchase manufactured products.

In the regulations listed above, the FDA states that spices, natural flavors, and/or artificial flavors may be listed in a vague manner. An example of this problem would be that most commercial products on the market contain ingredients such as modified food starch and/or natural flavorings. It is not possible to tell by this type of labeling what ingredients the product actually contains (such as corn, potato, or wheat, which are common allergens). **This type of labeling can have serious ramifications to an individual with food allergies, the most serious consequence being asphyxiation from undisclosed ingredients.** I, along with many other individuals who suffer from food allergies, urge the FDA to require manufacturers to list all ingredients, including trace amounts. My recommendation would be simply to add a line after the words modified food starch, natural flavorings, artificial flavoring, and/or any ingredient that is not listed in a clear manner, by telling what it is derived from. An example of this would be "modified food starch (derived from wheat);" or to substitute the vague term with a more specific term. An example of this would be "modified wheat starch" instead of "modified food starch," or "garlic oil" rather than "spices."

Possible environmental impact: None known.

Possible economic impact: We believe that initially this may cause some economic strain, as manufacturers may be required to investigate more into what ingredients are present in their products. Individuals with allergies may also refrain from purchasing products that they discover, via more indepth labeling, contain their allergens.

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.

Melissa J. Taylor

Melissa Taylor
foodallergy.what.cc

Food Allergy Survivors Together Co-founder

Contacts:
Lucy Shriver

<http://www.geocities.com/HotSprings/2579>
The Gluten-Free Kitchen Founder/Petition Author

Also, Melissa of FAST (listed previously).

Please add your own comments to the FDA. They are interested in your suggestions and experiences.

Jamie is only 5 years old + has been diagnosed with a life threatening peanut allergy. It is frightening to know that she could die by putting a product into her mouth which contained hidden, substituted or unlabeled peanut products (or which has been cross contaminated in a factory which produces peanut + non-peanut products.) We are doing all we can to help our little girl live a normal life, but if you do not do your part her life will always be at risk. If you have a child or love one, you can understand our plea and position. Thank you.

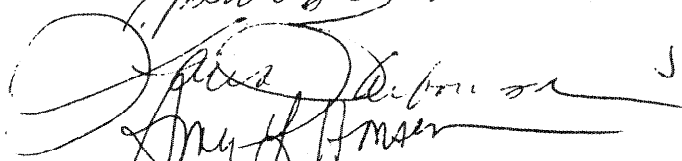
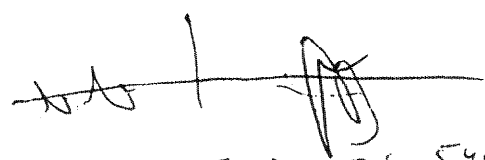
Signature Fran Stevens for Jamie Stevens

Name Printed Fran Stevens for Jamie Stevens

Mailing Address 7661 S. Avenida de Pina

City, State, Zip Tucson, AZ 85747

Telephone Number 520-647-3823

Jane & Elia
Mitch Stevens

Amy H. Maer
Harvest Situations
Gary Floyd
Bowl City

JAMIE STEVENS 5yrs.