

RE-GUIDANCE FOR INDUSTRY
Ingredients Lists Label Change

January 10, 2022

Division of Dockets Management
Food and Drug Administration
Health and Human Services
5630 Fishers Lane Room 1060 Rockville Maryland

10.30 Citizen Petition - Asking FDA to make changes to existing Guidance for Industry in regard to food label ingredients lists. In compliance with FOIA.

A. Action Requested

This petition requests the Commissioner to make changes to an existing Guidance for Industry requirement. This

Existing regulation found in the **Ingredients Lists** section of **Guidance For Industry**.

Verbatim: ""10. How are Spices, natural flavors or artificial flavors declared in ingredients lists?

Answer: These may be declared in ingredient lists by using either specific common or usual names or by using the declarations "spices," "flavor", or "natural flavor," or "artificial flavor".

"INGREDIENTS: Apple Slices, Water, Cane Syrup, Corn Syrup, Modified Corn Starch, Spices, Salt, Natural Flavor, and Artificial Flavor"

However, products that are spices or spice blends, flavors or colors must list each ingredient by name. FD&C Act 403(i)(2) and 212 CFR 101.22(h)(1) ""

This petition requests the Commissioner to amend regulation in this way:

""10. How are Spices, natural flavors or artificial flavors declared in ingredients lists?

Answer: These may be declared in ingredient lists by using either specific common or scientific names. All products or ingredients of products that are spices or spice blends, flavors or colors must list each ingredient by scientific name.

"INGREDIENTS: Apple Slices, Water, Cane Syrup, Corn Syrup, Modified Corn Starch, Spices, Salt, Ascorbic Acid, and Acesulfame K"

FD&C Act 403(i)(2) and 212 CFR 101.22(h)(1).

B. Statement of Grounds

- a. I rely on FD&C Act 403(i)(2) and 21 CFR 101.22(h)(1). And the Freedom of Information Act. Under section 303(c)(2) of the 21 CFR 101.22 "(4) A flavor supplier shall certify, in writing, that any flavor he supplies which is designated as containing no artificial flavor does not, to the best of his knowledge and belief, contain any artificial flavor, and that he has added no artificial flavor to it. The requirement for such certification may be satisfied by a guarantee under section 303(c)(2) of the act which contains such a specific statement. A flavor user shall be required to make such a written certification only where he adds to or combines another flavor with a flavor which has been certified by a flavor supplier as containing no artificial flavor, but otherwise such user may rely upon

the supplier's certification and need make no separate certification. All such certifications shall be retained by the certifying party throughout the period in which the flavor is supplied and for a minimum of three years thereafter, and shall be subject to the following conditions:

(i) The certifying party shall make such certifications available upon request at all reasonable hours to any duly authorized office or employee of the Food and Drug Administration or any other employee acting on behalf of the Secretary of Health and Human Services. Such certifications are regarded by the Food and Drug Administration as reports to the government and as guarantees or other undertakings within the meaning of section 301(h) of the act and subject the certifying party to the penalties for making any false report to the government under 18 USC § 1001 and any false guarantee or undertaking under section 303(a) of the act. The defenses provided under section 303(c)(2) of the act shall be applicable to the certifications provided for in this section.

(ii) Wherever possible, the Food and Drug Administration shall verify the accuracy of a reasonable number of certifications made pursuant to this section, constituting a representative sample of such certifications, and shall not request all such certifications."

And Good moral judgment by the commissioner to assume that we the people need to know what we are eating and drinking. Chemicals that we consume ought not be cloaked under the umbrella term Natural Flavor. There are thousands of chemicals that sit under this term, and we need the knowledge to make the right dietary decisions. Without that knowledge we cannot protect ourselves from chemicals that we may be personally allergic to or may be in fact generally harmful when consumed for long periods of time.

- b. Not much is unfavorable to this petition's position. The food manufacturers will want to be honest because their brand relies on it. This will only create a more competitive market as we evolve as a society that values less-processed foods and evidence-based decision making.

C. Environmental Impact

- a. No E.I. assessment is necessary, or one can be made upon request. I claim categorical exclusion under 25.30-.34 or 25.40.

D. Economic Impact

- a. Economic impact will be submitted upon request of the Commissioner

E. Certification

I certify to the best knowledge and belief 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 petitioner.

Connor Carmichael

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