



Calorie Control Council

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June 27, 2000

Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
rm. 1061  
Rockville, Maryland 20852

Re: Docket No. 99N-2497; Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action; 64 Federal Register 66822; November 30, 1999.

The Calorie Control Council provides the following comments on the Food and Drug Administration's request for comments on proposed amendments to its procedural regulations for the handling of Citizen Petitions. The Council is also in support of the comments submitted by the National Food Processors Association. The Council is an international association of manufacturers of low-calorie and reduced fat foods and beverages, including the manufacturers and users of a variety of alternative sweeteners, fat replacers and low-calorie bulking agents.

According to the above-mentioned Federal Register notice, FDA is proposing to amend its regulations pertaining to Citizen Petitions. The Council understands that FDA has limited resources and agrees that the Citizen Petition process should be improved. However, the Council concurs with the comments submitted by the National Food Processors Association's (NFPA) on this notice that the proposed action would frustrate the purposes and objectives of the Federal Food, Drug, and Cosmetic Act (FFDCA) by limiting the ability of regulated companies and consumers to seek amendment of the agency regulations, regardless of their substance, and other appropriate administrative action in a meaningful and legally binding way. The proposed changes will not eliminate frivolous petitions or petitions that request actions the agency cannot take legally or would not consider for good policy reasons. Moreover, none of the proposed changes will relieve the agency of its obligation to review and respond to any petitions properly filed. Proposing to change a system that has facilitated reasonably effective public participation in the agency's rulemaking and related processes for more than twenty years poses a real risk of creating possibly unintended and undesirable consequences. The Council, too, recommends that the agency use its limited resources to refine and implement the existing citizen petition process more efficiently.

The FDA regulates food labeling, as well as food safety. Limiting the use of the Citizen Petition to food safety issues is far too restrictive. Limiting this course of action would result in an absence of an effective mechanism to request changes in food labeling, standards of identity, and other economic regulations of particular interest to the consumer and industry.

Specifically, proposed §10.30(e)(2)(ii) – "Denial of Citizen Petitions" would provide that FDA's denial of a citizen petition may be "brief, as appropriate." At 64 FR 66824, FDA provides examples where the agency envisions a brief response denying a petitioner's request may be appropriate. The list includes:

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“3. A citizen petition where the agency has determined that the petition does not implicate a significant public health issue, and the agency lacks the resources to provide a more detailed response or to take the action requested by the petitioner. This may occur, for example, where the petitioner requests a change in FDA’s regulations that has no significant public health implications, such as amending or establishing common or usual names regulations or standards of identity, quantity, and fill of container regulations for foods . . . . In the absence of a significant public health issue, and considering the intense demand on FDA’s resources, the agency must allocate its resources carefully and wisely, so brief denial of these types of citizen petitions would be appropriate.”

Similarly, proposed §10.30(e)(4)(i)(D) would allow FDA to refer a Citizen Petition “for other administrative action instead of issuing a response” if the Petition “[d]oes not involve a significant public health or consumer protection issue.”

Granting FDA the ability to dismiss summarily a legitimate request to amend or establish common or usual name regulations, standards of identity or food labeling regulations can eliminate the only recourse available to a company seeking to develop and market a new product. Granting FDA the ability to refer such a request “for other administrative action” would have the same functional result. Indeed, seeking to amend a standard of identity is the only means a company has for marketing a new form of a product covered by a standard of identity. FDA has maintained that the only acceptable course of action for marketing a product which is different from the product described in the standard of identity is by seeking and obtaining a Temporary Marketing Permit (TMP) under 21 CFR §130.17. The regulations (§130.17(b)) state that: “It is the purpose of the Food and Drug Administration to permit such tests when it can be ascertained that the sole purpose of the tests is to obtain data necessary for reasonable grounds in support of a petition to amend food standards . . . .” Thus the only legitimate reason for obtaining the permit is to seek an amendment to the standard of identity. FDA’s proposal would permit the Agency to reject a request for a temporary marketing permit on the grounds that the Agency has insufficient resources to address any Citizen Petition that might ensue from such a permit. A similar position might be taken with respect to the use of innovative ingredients providing fewer calories or fat than traditional ingredients. If there is no mechanism to amend standards and labeling requirements to reflect the incorporation of such ingredients, the development and use of such ingredients will be stymied.

There is concern that FDA may elect to use this amendment to eliminate existing Citizen Petitions to reduce their backlog. The Council has withdrawn existing petitions when they are no longer pertinent, as when the request has been addressed in another manner. The Council is, however, concerned that Citizen Petitions directed to food standards and food labeling are infrequently placed on FDA’s priority list and there is no statutory time limit for addressing such petitions. Issues of concern addressed now in many citizen petitions would have even less chance of being addressed should FDA codify the changes suggested in the current notice. As NFPA noted on the issue of standards of identity, “A number of existing standards presently serve as barriers to the utilization of new technologies and ingredients to improve existing products. This, in turn, has made it difficult for the U.S. to promote an effective U.S. position at recent Codex Committee meetings, in light of the outmoded standards now in place . . . .” This argument would also apply in the future to labeling issues.

The Council further agrees with NFPA that creating obstacles to amending food standards of identity so as to render any such changes impracticable, a likely consequence of a rule resulting from the Citizen Petition initiative as proposed, would not remove the Agency's statutory authorities and obligations, or industry's rights, with respect to food standards of identity. Section 401 of the FFDCFA provides for the establishment of these standards, and the Council like NFPA is unaware of any lawful means by which a procedural regulation can void authority under the statute.

The Council supports the NFPA request that FDA expressly rescind the preamble language quoted above, from 64 FR 66824. The Council also supports the NFPA further request that FDA delete in its entirety proposed §10.30(e)(4)(i)(D) "Does not involve a significant public health or consumer protection issue." As NFPA has stated, one of the prerequisites for amending a standard of identity is that the amendment to the standard would not create a public health or consumer protection issue.

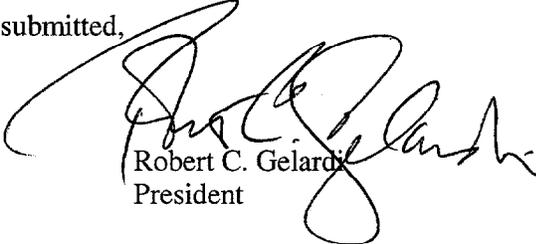
The Calorie Control Council, NFPA and the food industry in general have strongly supported the allocation of additional resources for CFSAN as a part of the appropriations process. We believe that the agency should allocate its available resources in such a way that it could address all of its responsibilities.

In summary, the Council, like NFPA, opposes any FDA action to reject summarily a Citizen Petition based solely on the grounds that the Agency lacks sufficient resources to respond to the action requested. The Council, also like NFPA, opposes any FDA action to refer Citizen Petitions that do not involve significant public health or consumer protection issues for other administrative action, rather than responding to the petition.

Thank you for considering the Council's comments and support for the NFPA's comments.

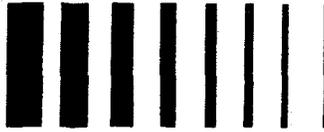
Respectfully submitted,

  
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