



INTERNATIONAL JELLY & PRESERVE ASSOCIATION

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Founded in 1918 as
National Preservers Association

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August 8, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 99N-2497; Citizen Petitions; Actions That Can Be Requested by
Petition; Denials; Withdrawals, and Referrals for Other Administrative Action

The International Jelly & Preserve Association (IJPA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) notice, "Citizen Petitions; Actions That Can Be Requested by Petition; Denials; Withdrawals and Referrals for Other Administrative Action" (64 *Federal Register (FR)* 66822; November 30, 1999). IJPA is a national trade association representing the manufacturers of jellies, jams, and preserves, and nonstandardized fruit spreads, and the suppliers of goods and services to the industry, including ingredient suppliers of fruit, sweeteners and pectin. A list of IJPA's manufacturer members is enclosed.

IJPA can appreciate FDA's desire to streamline the Citizen Petition process in light of current resources to review such petitions. However, any changes must be consistent with the Federal Food, Drug and Cosmetic Act (FFDCA), and be equitable to both consumers and the food industry. To that end, the National Food Processors Association (NFPA) expressed valid concerns in their February 28 comments regarding proposed changes to the Citizen Petition process, noting the proposed action would "frustrate the purposes and objectives of the [FFDCA] by limiting the ability of regulated companies and consumers to seek amendment of the Agency's regulations, regardless of their substance, and other appropriate administrative action in a meaningful and legally binding way." IJPA shares NFPA's concerns.

In particular, there is concern that through this proposal, FDA would be able to dismiss requests to amend or establish standards of identity or take action in other areas of economic adulteration. Proposed Section 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." Similarly, proposed Section 10.30(e)(2)(ii) would

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99N-2497

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provide that FDA's denial of a citizen petition may be "brief, as appropriate," with the following example at 64 *FR* 66824:

"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."

IJPA opposes the Agency's position that the decision to amend standards of identity regulations be based solely on resources not previously committed to "significant public health issues". Further, limiting the use of the Agency's resources to focus on Citizen Petitions dealing solely with food safety is unacceptable. In their comments regarding the proposed changes to the Petition process, NFPA accurately states: "...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 FFDCA provides for the establishment of these standards..." NFPA goes on to state that they are unaware "of any lawful means by which a procedural regulation can void authority under the statute."

It is evident from comments received on the Agency's previously published Advance Notice of Proposed Rulemaking (ANPRM) on food standards (60 *FR* 67492; December 29, 1995) that a number of existing standards presently serve as barriers to the utilization of new technologies and required ingredients to improve existing products. As a result, petitions have been prepared and filed in several important product categories to affect needed amendments to recognize the advances in food technology and the need for flexibility.

Three years ago, the Association submitted a Citizen Petition which reflected the consensus reached within the fruit spread industry on how FDA should proceed in implementing the ANPRM with respect to the standards of identity of interest to this industry. The petition requested that the standards for artificially sweetened jellies and jams be repealed because the standards were obsolete and unnecessary. IJPA submitted the petition on March 31, 1997, and to date,

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no action has been taken by the Agency, despite the fact that the Association offered a solution to streamline the standards for these products. Further, IJPA has been notified that FDA will not act on the petition within the required statutory time limitation.

It appears that FDA still acknowledges the importance of updating standards to reflect new technologies. In other Agency action, IJPA was pleased to note that FDA has included an item related to food standards of identity on the priority list for CFSAN's priorities for the fiscal year 2000. Item 2 on the "B" list for Strategy 2.2 – Nutrition, Health Claims and Labeling is to "develop a coordinated plan between FDA and USDA to correlate existing food standards with current technological innovations." IJPA agrees with this goal and urges prompt attention to unresolved Citizen Petitions. Similarly, obsolete standards, such as those for artificially sweetened jellies and jams, should be repealed.

In conclusion, IJPA supports NFPA's opposition to any FDA action to reject a Citizen Petition based on insufficient Agency resources or to refer Citizen Petitions that do not involve significant public health or consumer protection issues for other administrative action, rather than responding. IJPA also supports NFPA's recommendation that the Agency use its limited resources to refine and implement the existing Citizen Petition process more efficiently. We encourage action in this area and in the area of response to existing Citizen Petitions, such as IJPA's March 1997 petition.

We appreciate the opportunity to provide comments on this notice.

Sincerely,



Pamela A. Chumley
President

PAC/jcm

ACTIVE MEMBERS

International Jelly & Preserve Association

American Spoon Foods

Clements Foods Company

T.W. Garner Food Company

M.A. Gedney Company

House of Webster, Inc.

Smucker Specialty Foods, Inc.

Knott's Berry Farm Foods

The Kroger Company

The Red Wing Company, Inc.

Red Wing - California

Safeway

The J.M. Smucker Company

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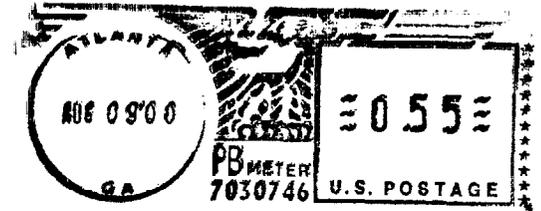
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