DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

2011 OCT 11 A 11:53

Ms. Kristen C. Gunter, Esquire
Macfarlane Ferguson & McMullen
1501 South Florida Avenue
Lakeland, Florida 33803

OCT 05 2011

Re: Docket No. FDA-2006-P-0207

Dear Ms. Gunter:

This letter responds to your citizen petition filed on March 8, 2006, on behalf of American Beekeeping Federation, Inc., American Honey Producers Association Inc., National Honey Packers and Dealers Association, Sioux Honey Association, and Western States Honey Packers and Dealers Association, seeking a U.S. standard of identity[1] for honey based upon the 2001 Revised Codex Alimentarius Commission (Codex) Standard for Honey (CODEX STAN 12-1981, Rev. 2 (2001)), and invoking the review procedure set forth in Title 21 of the Code of Federal Regulations (CFR), section 130.6 (21 CFR 130.6). Pursuant to 21 CFR 130.6(b)(1), you request that this petition be published in the Federal Register as a proposal.

As stated in 21 CFR 130.5(a), the procedure for establishing a food standard under section 401 of the Federal Food, Drug, and Cosmetic Act (the Act) is governed by 21 CFR Part 10. In accordance with 21 CFR 10.30(e)(3), this letter is to advise you that the Food and Drug Administration (FDA) is denying your petition.

21 CFR 130.6(b)(1) states in part:

Any interested person may petition the Commissioner to adopt a Codex standard, with or without change, by proposing a new standard or an appropriate amendment of an existing standard, pursuant to section 401 of the act. Any such petition shall specify any deviations from the Codex standard, and the reasons for any such deviations. The Commissioner shall publish such a petition in the Federal Register as a proposal, with an opportunity for comment, if reasonable grounds are provided in the petition. Any published proposal shall state any deviations from the Codex standard and the stated reasons therefor.

[1] To promote honesty and fair dealing in the interest of consumers, food standards of identity describe the basic nature and reflect the essential characteristics of a food, consistent with consumer expectations. FDA establishes food standards of identity under authority set forth in section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). This section provides in part:

> Whenever in the judgment of the Secretary [of Health and Human Services] such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container.

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FDA has concluded that your petition does not provide reasonable grounds for FDA to adopt the Codex standard for honey (with the deviations set forth in your petition). FDA has further concluded that the Agency's existing enforcement tools are sufficient to address the concerns set forth in your petition, and that the establishment of a standard of identity for honey would not aid the Agency in its enforcement efforts or help ensure industry compliance.

The first argument made in your petition is that the requested standard of identity for honey would promote honesty and fair dealing in the interest of consumers,[2] because consumers are confused about what the term "honey" means in terms of the food's composition. Specifically, you assert that many consumers believe that pure honey contains additives and that honey contains added syrup.[3] However, to the extent that consumers are confused about what honey is and what it contains, the food label provides the relevant information to alleviate consumer confusion. FDA has concluded that establishing a standard of identity for honey would not provide additional assurance that consumers would be informed about what honey is. Therefore, the argument that consumers are confused about what honey is does not provide reasonable grounds for FDA to establish a standard of identity for honey.

A properly labeled food informs consumers what the food is and what it contains. In particular, section 403(i) of the Act provides that a food is misbranded unless its label bears (1) the common or usual name of the food, and (2) the common or usual name of each ingredient, if the food is fabricated from two or more ingredients. In addition, FDA's regulation in 21 CFR 102.5(a) provides that the common or usual name of a food must accurately identify or describe the basic nature of the food or its characterizing properties or ingredients. As defined in the 2010 edition of Webster's New World College dictionary,[4] honey is "a thick, sweet, syrupy substance that bees make as food from the nectar of flowers and store in honeycombs." FDA has concluded that this definition accurately reflects the common usage of the term "honey." A properly labeled package of honey bears the name of the food as "honey" (or perhaps as a name that indicates the source of the honey, such as "Clover Honey")[5], while a food that is a

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[2] Your petition correctly notes that the promotion of "honesty and fair dealing in the interest of consumers" is one of the 13 proposed general principles for food standards that are set forth in the proposed amendments to 21 CFR 130.5 that were published in 70 FR 29214 (May 20, 2005). You offer to submit a comprehensive statement showing compliance with each of the 13 proposed general principals. This is not necessary, in light of the fact that these proposals have not been finalized. However, your analysis of how your proposed standard of identity for honey would promote honesty and fair dealing in the interest of consumers is relevant to our consideration of your petition, since that is the statutory standard set forth in section 401 of the Act. (See footnote one.)

[3] You base this contention on a consumer survey conducted by the National Honey Board. According to your summary of this survey, 42 % of consumers thought that pure honey contained additives and 17% of those surveyed thought that honey contained added syrup.

[4] Webster's New World College Dictionary Copyright © 2010 by Wiley Publishing, Inc., Cleveland, Ohio. Used by arrangement with John Wiley & Sons, Inc.

[5] FDA's Compliance Policy Guide Section 515.300, available at http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074437.htm, states: "A honey may be labeled with the name of the plant or blossom provided that the particular plant or

mixture of honey and syrup would bear a name such as "blend of honey and syrup." Furthermore, when a food is composed of two or more ingredients, such as honey and syrup or honey and other additives, the label must also bear an ingredient list stating the common or usual name of each ingredient. Therefore, it is the label that informs customers of whether a honey product consists only of honey or whether it is a mixture of honey and other ingredients. To the extent that consumers do not have knowledge of honey or do not read the label, FDA has concluded that establishing a standard of identity for honey would not eliminate consumer's confusion on what honey is, since individual consumers would be unlikely to be aware that a standard of identity exists, nor would they be likely to seek it out as a means of addressing their confusion.

The second argument made in your petition is that a U.S. standard of identity for honey would serve as a tool to combat economic adulteration. You cite a study of the impacts of economic adulteration on the United States honey industry, which you state found that the economic adulteration of honey had the effect of expanding supply and therefore would reduce the price of honey as well as producer revenue. However, you do not explain how a standard of identity for honey would help prevent economic adulteration. Your petition states that "to the extent that a clear honey standard would aid enforcement and industry compliance, reduced economic adulteration will benefit both consumers and producers." But you do not explain how a honey standard would "aid enforcement and industry compliance."

FDA's existing authority addresses economic adulteration. According to section 402(b) of the Act, a food is deemed to be adulterated if any valuable constituent has been omitted in whole or in part or if any substance has been added so as to reduce the quality of the food or make it appear to be better or of greater value than it is. Therefore, FDA can take enforcement action against honey products that contain added substances that render the products economically adulterated. In addition, as previously discussed, if a honey product contains an added substance, such as syrup, the food product must bear on the label a name that accurately identifies or describes the basic nature of the food or its characterizing properties or ingredients (*e.g.*, "blend of honey and syrup") and an ingredient list that declares all ingredients, namely, honey and syrup; otherwise, the honey product would be deemed misbranded under section 403(i) of the Act. In this case, FDA can take enforcement action against the honey product for being misbranded. We conclude that these existing enforcement tools are sufficient to combat the economic adulteration of honey, and we do not find that establishing a standard of identity for honey would aid the Agency in its enforcement efforts or help to ensure industry compliance.

The third argument made in your petition is that adopting a standard of identity for honey will promote honesty and fair dealing within the food trade in general, where pure honey

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blossom is the chief floral source of the honey, such as 'Orange Blossom Honey' or 'Clover Honey,' and provided that the honey producer is in a position to demonstrate that the plant or blossom designated on the label constitutes the chief floral source of the honey."

is used as an ingredient in other foods.[6] To the extent that consumers will pay more for foods made with real honey and that real honey is highly valued as an ingredient in foods, this consumer appreciation of honey does not provide a basis for FDA to establish a standard of identity for honey. Consumers can be informed that a food product contains honey by reading the ingredient list of the food product. Although it is true that some products might not be accurately labeled, having a standard of identity for honey would not offer any additional assurance that a given product is accurately labeled, nor would it provide any additional enforcement authority beyond what exists for misbranded foods.

In summary, your petition does not provide reasonable grounds for FDA to adopt the Codex standard for honey (with the deviations set forth in your petition). While the Agency shares your concerns about adulterated and misbranded honey, we have concluded that establishing a standard of identity for honey would not help address the issues you raise, nor would it help promote honesty and fair dealing in the interest of consumers. Your stated goals are: 1) informing consumers who are confused about what "honey" means in terms of the food's composition; 2) combating economic adulteration by aiding enforcement and industry compliance; and 3) promoting honesty and fair dealing within the food trade in general, where pure honey is highly valued as an ingredient in other foods. These goals can all be achieved using existing FDA enforcement tools, and after evaluating your petition, we have concluded that having a standard of identity for honey would not provide any additional support toward the achievement of these goals. We therefore conclude that your petition does not provide reasonable grounds for FDA to publish it as a proposal under 21 CFR 130.6.

Because we share your concerns regarding the adulteration and misbranding of honey, we intend to issue guidance to industry reminding firms that honey must not be adulterated or misbranded in accordance with sections 402 and 403 of the Act. We will continue to monitor the industry and take appropriate action on honey that is adulterated or misbranded. FDA has a long-standing import alert (Import Alert #36-01, available at http://www.accessdata.fda.gov/cms_ia/importalert_108.html) for surveillance of honey for adulteration with cane or corn sugars. As resources permit, FDA field personnel are instructed to monitor imported honey for adulteration with these sweeteners.[7]

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[6] Your assertion is based on a study conducted by the National Honey Board, which you summarize as showing that consumers will pay more for foods made with real honey and that real honey is highly valued as an ingredient in foods.

[7] In addition, FDA has import alerts recommending that field personnel detain without physical examination imported honey that appears to contain (based on sample results from a previous shipment) residues of the drugs chloramphenicol and fluoroquinolones. At present, there are 13 firms covered by the import alert for chloramphenicol residues in honey (Import Alert #36-03, available at http://www.accessdata.fda.gov/cms_ia/importalert_110.html) and 18 firms covered by the import alert for fluoroquinolone residues in honey and blended syrups (Import Alert #36-04, available at http://www.accessdata.fda.gov/cms_ia/importalert_111.html). FDA has included testing of honey for these two residues in its routine chemical contaminant monitoring program.

In conclusion, FDA is denying your petition for the reasons given above.

Sincerely yours,

Donald W. Kraemer
Acting Deputy Director for Operations
Center for Food Safety
and Applied Nutrition