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IN REPLY REFER TO:

March 3, 2006

Lakeland

Dockets Management Branch
United States Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

*Re: Petition for Review of Codex Standard for Honey Under 21 CFR 130.6 by
Petitioners American Beekeeping Federation, et al*

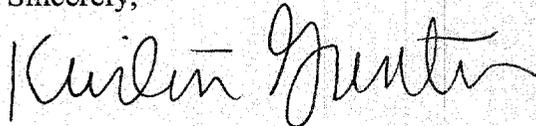
Dear Sir or Madam:

Please find enclosed for filing an original plus three copies of the above styled Petition to FDA.

We would appreciate stamped receipt of this submission and enclose an additional copy of the petition with a self addressed stamped envelope for this purpose.

If you have any questions or we need to do anything additional to secure the filing, please inform us at the address indicated on the face of the Petition and this letterhead or by calling us at (863) 680-9908. Thank you for your assistance.

Sincerely,



Kristen C. Gunter

Enclosure

2006P-0101

CP 1

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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Citizen Petition to

Andrew C. von Eschenbach, M.D.,
Commissioner of Food and Drugs

Docket No.

For Review of **Codex Alimentarius**
Standard for Honey, Pursuant to 21 CFR 130.6

Submitted by the

American Beekeeping Federation, Inc.
American Honey Producers Association Inc.
National Honey Packers and Dealers Association
Sioux Honey Association
Western States Honey Packers and Dealers Association

March 3, 2006

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Dockets Management Branch
United States Food and Drug Administration
Department of Health and Human Services
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I. Introduction

The U.S. Food and Drug Administration ("FDA") and other U.S. interests participate in the development of international standards by the Codex Alimentarius Commission, an international organization formed in 1962 to facilitate world trade. In 2001, the Revised Codex Standard for Honey was adopted by the 24th Session of the Codex Alimentarius Commission. The United States participated fully in the proceedings. While honey is produced in the U.S., traded internationally and consumed both as a packaged food and as a food ingredient, there currently is no standard of identity for honey in U.S. law.

Petitioners are trade associations (a description of each association petitioner is attached as Exhibit "A") whose members are engaged in the businesses of production, importing, exporting, packaging and marketing of honey to both consumers as finished product and to manufacturers, who use honey as an ingredient in other foods. Petitioners seek a U.S. standard for honey based upon the 2001 Revised Codex Standard for Honey and invoke the review procedure set forth in 21 CFR 130.6. With the adoption of such requested standard, Petitioners expect that consumers and industry alike will accrue the presumed benefits of the international standard, and hopefully, the identity and traditional composition of honey will be preserved in a market of many new liquid sweeteners.

Although FDA has much experience in promulgating standards of identity, there is less specific experience and guidance in promulgating Codex standards into U.S. law. Petitioners are mindful of the process outlined in 21 CFR 130.5 for adoption of standards of identity and the possible applicability of FDA's proposed amendments to 21 CFR 130.5 to the separate 21 CFR 130.6 process for review of Codex standards. A discussion of these issues is covered below in Part IV of this petition.

Finally, by way of introduction, a description of how honey is produced and a brief description of the U.S. honey industry is attached as Exhibit "B".¹

II. Action Requested

This petition requests action by the Commissioner pursuant to 21 CFR 130.6 to adopt certain provisions of the Codex Standard for Honey (*CODEX STAN 12-1981, Rev.2 (2001)*), pursuant to 401 of the Federal Food Drug and Cosmetic Act. A copy of the Codex Standard for Honey with requested deviations is attached hereto as Exhibit "C." Petitioners request the Commissioner to publish this Petition in the Federal Register as a proposal.

III. Reasons for Deviations

Petitioners request certain deviations from the Codex Standard for Honey. Referring to Exhibit C, the reasons for the deviations requested are as follows:

1. USITC Publication 3369, November 2000

1. Scope.

Delete the Voluntary Annex to the Standard because it is for commercial use only and not for application by Governments.

Delete from the scope the proposed separate standard in Part Two for honey for industrial uses since this standard has not been completed and this variation can be consolidated into the single standard for honey. The need for reference to two separate parts will thus no longer be necessary.

3. Essential Composition and Quality Factors

Section 3.4 Moisture Content

Delete subsections (a) and (b) replace the section with revised text that provides that no honey should have a moisture content exceeding 23% (or less than 77% dissolved soluble solids.) This moisture level is consistent with current U.S. honey and commercial practices and will preserve the integrity, quality and value that U.S. consumers expect in honey. U.S.D.A. Grade standards for extracted honey currently provide stricter moisture content requirements for grades of honey than the maximum moisture content proposed herein.

4. Contaminants; 4.1 Heavy Metals and 4.2 Residues of Pesticides and Veterinary Drugs:

Delete Section 4.0. Contaminants and Maximum levels for heavy metals and pesticide residues should be governed by U.S. law.

5. Hygiene

Delete Section 5. Hygiene requirements should be governed by U.S. law.

6. Labeling and 6.2 Labeling of Non-retail Containers

6. Delete reference to Codex General Standard for Labeling or Pre-Packaged Foods. The U.S. labeling laws applicable to foods in retail containers and non-retail containers should apply rather than the Codex General Standard for Labeling of Pre-Packaged Foods.

6.1.1. Standards of identity are referenced throughout FDA regulations and the existence of a standard of identity can trigger application of laws not otherwise applicable to non-standardized foods. Petitioners request a review of U.S. laws to ascertain whether the laws which otherwise apply to foods prescribed under a standard of identity, (e.g. 21 CFR Part 130, labeling, adulteration, misbranding etc.), would also apply to the Honey Codex regulation if adopted into law. For example, Petitioners desire that foods which do not conform to the Honey Codex Standard (by virtue of added ingredients or modifications) be required to be distinguished from "Honey" through non-misleading common or usual name labeling, as would be the case for a food with a standard of identity. If FDA determines that any laws would not apply to the requested Honey standard simply because of the possible

designation of the standard as a "Codex standard" rather than as a standard of identity, we suggest that the issue be addressed in the text of the standard. See example of language in brackets.

6.1.11(c) provides that honey "style" may be designated according to the method of removal of the comb. According to the Codex honey standard in subparagraph 6.1.11(c), honey containing one or more pieces of comb may be designated as "cut comb in honey" or "chunk honey." In the United States, the designation for such honey most commonly used is "honey with comb." Petitioners seek FDA clarification that the designation "honey with comb" will remain lawful if the Codex text is adopted, or in the alternative, FDA should add the style designation "honey with comb" to the list of allowed style designations.

Delete 6.1.12. As filtration with some concomitant removal of pollen is the commercial norm for honey manufactured in the U.S. , such honey should not be required to be specifically designated as "filtered."

7. Methods of Sampling and Analysis

Delete entire Section 7.0. The U.S. government and regulatory authorities should enforce the standard using any methods deemed advisable and lawful.

ANNEX

Delete Annex. As the text in the annex is intended for voluntary application by commercial partners and not for application by governments, the Annex, in its entirety, should not be codified into U.S. law and should be deleted in its entirety.

IV. Statement of How the Proposed Standard Conforms to General Principles Outlined in Proposed Rules to 21 CFR Part 130.5; 70 F.R.29234 (May 20, 2005)

FDA has recently published proposed amendments to 21 CFR 130.5 at 70 F.R. 29234 prescribing approximately thirteen general principles governing the adoption of food standards. These proposed amendments may not technically apply to a petition for review of Codex standards under 21 CFR 130.6, however they merit comment in this Petition. When promulgating commodity standards, the Codex Alimentarius Commission applies many of the same general principles as those listed by FDA in the proposed rules published May 20, 2005. Petitioners respectfully submit that the Codex Alimentarius Honey Standard should be *ipso facto* proof of conformity to such similar general principles since conformity would be inherent in the Codex process. For this reason, we will not go into separate proof of adherence to each of the thirteen separate general principles in this petition. A comprehensive statement showing compliance with each of FDA's thirteen proposed general principals will be provided by supplement if FDA feels this information is required or advisable. In lieu of such a lengthy discussion, a few key points relative to two of the proposed general principles are as follows:

The first, and presumably the most important proposed general principle for agency consideration in the adoption of a food standard is consideration of whether the requested standard promotes honesty and fair dealing in the interest of consumers.

A consumer study conducted in 2005 for the National Honey Board suggests that U.S. consumers are very confused about what "honey" means in terms of the food's composition.² Forty-two percent of those interviewed believed that pure honey contains additives and 17% of those interviewed believed "honey" contains added syrup. With a variety of blended sweeteners and "honey pretenders" being introduced into the market, consumer understanding of the meaning of the term "honey" is likely to continue to erode. Thus, the codification of the identity statement "honey" is timely and sorely needed. The standard will preserve the food name of "honey" for the traditional food and clearly encourage the industry to promote the consumption of honey for its sensory and nutritive benefits that extend beyond its obvious role in the American diet as a natural sweetener.

Petitioners submit that the proposed standard will promote honesty and fair dealing not only in the interest of consumers, but in the interest of the honey industry as well. Petitioners particularly believe that a compositional standard for honey will serve as a tool to help combat the economic adulteration of honey.

According to a study of the impacts of economic adulteration on the U.S. honey industry, it was found that any significant level of adulteration would have the affect of expanding supply. For high value product like honey, absent a demand shift in the amount purchased at any given price, an increase in supply due to adulteration would result in downward price pressure and decreased producer revenue.³ Petitioners believe that to the extent that a clear honey standard would aid enforcement and industry compliance, reduced economic adulteration will benefit both consumers and producers.

Also, the proposed standard is expected to promote honesty and fair dealing within the food trade in general, where pure honey is used as an ingredient in other foods. A consumer study shows that consumers will pay more for foods made with real honey and highly value honey as an ingredient in foods.⁴

In regard to a second proposed general principle, the proposed food standard should take into account any other of FDA's relevant regulations. Please note that the requested Codex Honey standard takes into account FDA's other regulations by striking Codex language, which, otherwise might contravene FDA's regulations regarding labeling, hygiene, contaminants and analytical methods and suggests application of U.S. law.

² Topline Results, Honey Label Confusion Study; November 1, 2005; National Honey Board.

³ Fairchild, Gary F., John P. Nichols and Oral Capps Jr. *Journal of Food Distribution Research* Vol. 34 (2, 2003); 38-45 "Observations on Economic Adulteration On High Value Food Products: the Honey Case"

⁴ Honey Value Added Study for National Honey Board; March 2004; Jeffrey B. Gross

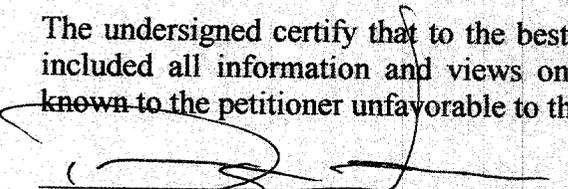
V. Statement of Meetings with Other Interest Groups

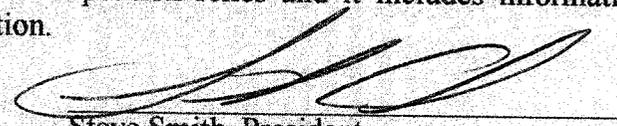
In formulating this petition, the Petitioners and other interest groups have conducted the following meetings, where the need for this action was either discussed or the petition itself discussed. These meetings do not include the numerous meetings where the honey industry participated in the extensive underlying Codex Alimentarius process to adopt the Revised Codex Honey Standard.

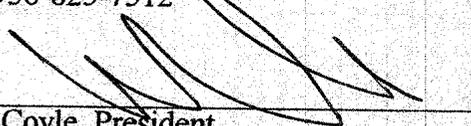
- Honey Industry Roundtable, December 2-3, 2004, San Antonio, TX; Sponsored by the National Honey Board
- The American Honey Producers Association, Inc., Annual Meeting, January 8, 2005, San Antonio, TX
- The National Honey Packers & Dealers Association, Annual Meeting January 6, 2005; Executive Committee meeting September 27, 2005
- American Beekeeping Federation, Inc. at Board of Directors meetings held June 6, 2004; July 22, 2004 and January 13, 2005
- Sioux Honey Association meeting held January 19, 2006
- Western States Honey Packers and Dealers Association meeting held January 5, 2006

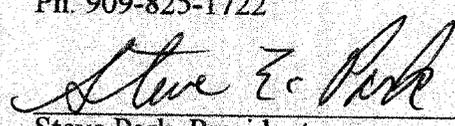
VI. Certification

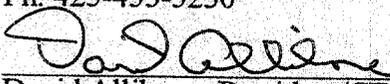
The undersigned certify that to the best knowledge and belief of the undersigned, this Petition included all information and views on which the petition relies and it includes information known to the petitioner unfavorable to the petition.


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UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Supplement to Citizen Petition to

**Andrew C. von Eschenbach, M.D,
Commissioner of Food and Drugs**

Docket No.

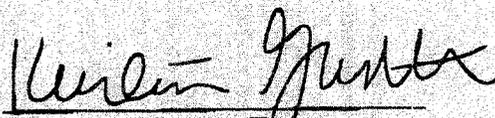
**For Review of Codex Alimentarius
Standard for Honey, Pursuant to 21 CFR 130.6**

Please find the following Supplement to the Petition:

Environmental Impact

Petitioners claim categorical exclusion from environmental assessment and environmental impact statement requirements because the action requested is of the type excluded pursuant to 21 C.F.R. §25.32(a).

The undersigned certifies to the best knowledge and belief of the undersigned, this supplement includes representative data and information known to the Petitioners that are unfavorable to the Petition.



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