Guidance for Industry

Proper Labeling of Honey and Honey Products

Draft Guidance

Additional copies are available from:
Food Labeling and Standards Staff (HFS-820)
Office of Nutrition, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 240-402-2371
http://www.fda.gov/FoodGuidances

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2371.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

April 2014

Table of Contents

Guidance for Industry[1]

Proper Labeling of Honey and Honey Products

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This guidance advises firms on the proper labeling of honey and honey products to help ensure that honey and honey products are not adulterated or misbranded under sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342 and 343).

In the remainder of this guidance, "you" refers to firms that manufacture, process, pack, or label honey and to persons who are authorized to act on behalf of such firms. "We" refers to FDA.

Our guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidance documents means that something is suggested or recommended, but not required.

II. Background

On March 8, 2006, the American Beekeeping Federation and several other honey-related associations submitted a citizen petition requesting that FDA adopt a U.S. standard of identity for honey based on the 2001 Revised Codex Alimentarius Commission's Standard for Honey (reference 1). The petitioners asserted that a U.S. standard of identity for honey would achieve the following goals: (1) clarify what the term "honey" means with respect to the food's

[1] This guidance has been prepared by the Food Labeling and Standards Staff, Office of Nutrition, Labeling, and Dietary Supplements in the Center for Food Safety and Applied Nutrition at FDA.

composition and therefore promote honesty and fair dealing in the interest of consumers; (2) combat economic adulteration of honey by aiding enforcement and industry compliance; and (3) promote honesty and fair dealing within the food trade in general, where pure honey is used as an ingredient in other foods.

In a letter of October 5, 2011, we denied the petition because the petition did not provide reasonable grounds for FDA to adopt the Codex standard for honey. We also concluded that the petitioners' goals can be achieved by our existing authorities and a standard of identity for honey would not promote honesty and fair dealing in the interest of consumers (reference 2). To address the labeling issues relevant to the petition and to reinforce existing laws and regulations to the industry, we are issuing this guidance document, which includes a summary of the current legal authorities that are most relevant to the labeling of honey and questions and answers on the labeling of honey.

Misbranding

Under section 403(i) of the FD&C Act, 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. The common or usual name for an ingredient is the name established by common usage or by regulation (21 CFR 102.5(d)). The common or usual name must accurately describe the basic nature of the food or its characterizing properties or ingredients, and may not be "confusingly similar to the name of any other food that is not reasonably encompassed within the same name" (21 CFR 102.5(a)). Moreover, under 21 CFR 101.4(a)(1), ingredients in a food must be listed on its label by common or usual name in descending order of predominance by weight. Furthermore, under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular.

Adulteration

Under sections 402(b)(1) through 402(b)(4) of the FD&C Act, a food is adulterated if a valuable constituent has been omitted in whole or in part from a food, or if any substance has been substituted wholly or in part, or if damage or inferiority has been concealed in any manner, or if a substance has been added to a food so as to increase its bulk or weight, reduce its quality or strength, or make it appear to be better or of greater value than it is. Furthermore, section 402(a)(2)(C) of the FD&C Act provides that a food is adulterated if it bears or contains a food additive that is unsafe within the meaning of section 409 of the FD&C Act or a new animal drug that is unsafe within the meaning of section 512 of the FD&C Act. To further provide guidance to industry on the proper labeling of honey and honey products in accordance with our laws and regulations, we have developed the following questions and answers.

III. Labeling of Honey: Questions and Answers (Q&A)

1. **What is honey?**

Reference materials in the public domain define honey as "a thick, sweet, syrupy substance that bees make as food from the nectar of flowers and store in honeycombs."[2,3] FDA has concluded that this definition accurately reflects the common usage of the term "honey."

2. **How shall I name my honey or honey product?**

   If a food contains only honey, the food must be named "honey," which is its common or usual name. The common or usual name may also include the source of the honey, such as "Clover Honey," on the label. (See Q&A 3 below.) Because honey is a single ingredient food, you do not need to include an ingredient statement on the label. However, you must include all other mandatory information (e.g., net weight).

3. **Do I have to declare the floral source of honey?**

   No. You do not have to declare the floral source of honey on the label. However, you may label the honey with the name of the plant or blossom, if:

   (a) The particular plant or blossom is the chief floral source of the honey, such as "Orange Blossom Honey" or "Clover Honey" and

   (b) You, or the honey producer, can show that the plant or blossom designated on the label is the chief floral source of the honey. (See FDA Compliance Policy Guide, section 515.300.)

4. **If a food consists of honey and a sweetener, such as sugar or corn syrup, can I label the food as only "honey"?**

   No, a product consisting of honey and a sweetener cannot be labeled with the common or usual name "honey." The food is a blend or a mixture of honey and another sweetener. You must sufficiently describe the name of the food on the label to distinguish it from simply "honey" (21 CFR 102.5(a)).

5. **If a food consists of honey and a sweetener, such as sugar or corn syrup, how shall I label the food?**

---

[2] Webster's New World College Dictionary, (Wiley Publishing, Inc., Cleveland, Ohio 2010). See also "Honey is a thick, sweet liquid made by bees from flower nectar." Sharon Tyler Herbst and Ron Herbst, The Deluxe Food Lover's Companion, (Hauppauge: New York, 2009), and Honey is a "sweet, viscous liquid food, dark golden in color, produced in the honey sacs of various bees from the nectar of flowers." Encyclopedia Britannica Online. 2012, available at: http://www.britannica.com/EBchecked/topic/270849/honey.

[3] The National Honey Board describes honey as "the natural sweet substance produced by honey bees from the nectar of plants or secretions of living parts of plants," including both nectar (floral) honey and honeydew honey, however, honey is more commonly known as the substance bees collect from nectar of plants. "Learn about Honey," The National Honey Board, available at: http://www.honey.com/honey-at-home/learn-about-honey/ .

For a food consisting of honey and a sweetener, you must label the food with:

(a) The common or usual name, which must be a name that accurately identifies or describes the basic nature of the food or its characterizing properties or ingredients; for example:
- "Blend of honey and sugar," if the food has more honey than sugar (likewise, "Blend of honey and corn syrup," if the food has more honey than corn syrup).
- "Blend of sugar and honey," if the food has more sugar than honey (likewise, "Blend of corn syrup and honey," if the food has more corn syrup than honey).

(b) The common or usual name of each ingredient in the ingredient statement. In this case, the label would show "honey" and "sugar," (likewise, "honey" and "corn syrup") in descending order of predominance by weight in the ingredient statement because the food is made from two or more ingredients (see section 403(i) of the FD&C Act, 21 CFR 102.5(a), and 21 CFR 101.4(a)(1)).

(c) All other mandatory labeling information (e.g., net weight).

6. **If a food consists of honey and another ingredient, such as natural raspberry flavor, how shall I label the food?**

For a food consisting of honey and another ingredient, such as natural raspberry flavor, you must label the food with:

(a) The common or usual name, which must be a name that accurately describes the food, such as "raspberry flavored honey."

(b) The common or usual name of each ingredient, in this case, "honey," and "natural flavor." (See section 403(i) of the FD&C Act, 21 CFR 102.5(a), and 21 CFR 101.22(h)(1).)

7. **How would consumers know whether the food is honey, a blend of honey and another sweetener (e.g., sugar or corn syrup), or honey that contains flavoring agent (e.g., natural raspberry flavor) or other ingredients?**

Consumers would know what the food is and what the food contains by reading the label. A properly labeled package of only honey would show the name of the food as "honey," and it would not need an ingredient statement because it would only contain one ingredient. In comparison, a properly labeled package of a blend of honey and a sweetener would have a name such as "blend of honey and sugar" (likewise, "blend of honey and corn syrup") and an ingredient statement that lists each ingredient, such as "honey" and "sugar" (likewise, "honey" and "corn syrup"). Similarly, a properly labeled package of honey with natural raspberry flavor would have a name such as "raspberry flavored honey" and an ingredient statement that lists each ingredient, such as "honey" and "natural flavor."

8. **How would consumers know if a food product that contains two or more ingredients contains honey?**

   Consumers would know that a food product contains honey by reading the ingredient statement. A properly labeled food product would list the ingredient by its common or usual name, "honey," in the ingredient statement.

9. **What enforcement authorities does FDA have for food products that are represented as "honey," but contain other ingredients?**

   FDA's enforcement authorities for food products that are represented as "honey," but contain other ingredients, are described below.

   Case A: A product is labeled as "honey," but it contains natural raspberry flavoring. The ingredient statement lists only "honey."

   According to section 403(i) of the FD&C Act, a food is misbranded unless the 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 made from two or more ingredients. In this case, the name of the food "honey" does not accurately describe that the food is a raspberry flavored honey, which is a characterizing flavor; this is not an appropriate common or usual name under 21 CFR 102.5(a). Moreover, the ingredient statement lists only one ingredient, "honey," when the food contains "honey" and "natural flavoring." Therefore, FDA can take enforcement action against the food for being misbranded.

   Case B: A product is labeled as "honey," but it contains honey and another sweetener, such as sugar or corn syrup. The ingredient statement lists only "honey."

   Under section 402(b) of the FD&C Act, a food is 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. In this case, the food is represented as honey when another sweetener (e.g., sugar or corn syrup) has been substituted in part for honey. The food is then labeled as "honey." Honey is considered a more valuable food than a food that contains both honey and sugar (likewise, a food that contains both honey and corn syrup).[4] Therefore, we can take enforcement action against the food for being adulterated under section 402(b)(1) of the FD&C Act because a valuable constituent (honey) has been omitted in part, section 402(b)(2) of the FD&C Act because a substance (sugar or corn syrup) has been substituted in part, and/or under section 402(b)(4) of the FD&C Act because a substance (sugar or corn syrup) has been added to the honey so as to increase its bulk or weight or make it appear better or of greater value than it is.

[4] Honey is more valuable than other sweeteners. See "Sugar and Sweeteners Yearbook Tables," United States Department of Agriculture Economic Research Service. 2012, available at: http://www.ers.usda.gov/data-products/sugar-and-sweeteners-yearbook-tables.aspx.

Further, we may take additional enforcement action against the food for being misbranded under section 403 of the FD&C Act due to improper labeling of the food; i.e., the name of the food and the ingredient statement (see Case A and Q&A 5).

Case C: A product, labeled as "honey," contains residues of chloramphenicol and fluoroquinolones.

A food is adulterated if it contains residues of chloramphenicol or fluoroquinolones (see section 402(a)(2)(C) of the FD&C Act). Therefore, we can take enforcement action against honey that bears residues of chloramphenicol or fluoroquinolones for being adulterated.

10. **Some imported packages of honey are adulterated with cane or corn sugars while some are adulterated with residues of chloramphenicol and fluoroquinolones. How does FDA monitor such adulterated honey products?**

    We have a long-standing import alert for surveillance of honey for adulteration with cane or corn sugars. In addition, we have import alerts recommending that field personnel detain without physical examination imported honey that appears to contain residues of chloramphenicol and fluoroquinolones. Such a product would not be released into U.S. distribution until we determined that the product was not adulterated or misbranded.

IV. References

The following references are on display in the Division of Dockets Management, FDA, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

1. Citizen Petition filed by Kristen C. Gunter, Esquire, Macfarlane Ferguson & McMullen, on behalf of five trade associations (American Beekeeping Federation, American Honey Producers Association, National Honey Packers and Dealers Association, Sioux Honey Association, and Western States Honey Packers and Dealers Association), March 3, 2006.

2. Letter from Donald W. Kraemer, Acting Director for Operations, Center for Food Safety and Applied Nutrition, FDA, to Kristen C. Gunter, Esquire, Macfarlane Ferguson & McMullen, October 5, 2011.