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Proper Labeling of Honey and Honey Products: Guidance for Industry

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U.S. Department of Health and Human Services
Food and Drug Administration
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Proper Labeling of Honey and Honey Products: Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance is intended to advise the regulated industry on the proper labeling of honey and honey products in accordance with sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342 and 343) and its implementing regulations. Accurate and consistent labeling of honey and honey products helps to ensure that honey and honey products are not adulterated or misbranded and enhances consumers' ability to make informed choices among products.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances 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 FDA guidances means that something is suggested or recommended, but not required. Throughout this guidance, "you" refers to firms that manufacture, process, pack, label, or distribute honey and honey products and to persons who are authorized to act on behalf of such firms.

II. Background

We are issuing this guidance document, which includes a summary of the current legal authorities that are most relevant to the labeling of honey, to address key questions and answers on the labeling of honey.

[1] This guidance has been prepared by the Office of Nutrition and Food Labeling, Food Labeling and Standards Staff, in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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, if there be any; 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 a food may be established by common usage or by regulation (21 CFR 102.5(d)). The common or usual name must accurately identify or describe, in as simple and direct terms as possible, 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 required to be declared on the label or labeling of 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 section 402(b) of the FD&C Act, a food is adulterated if: (1) a valuable constituent has been omitted in whole or in part from a food; (2) if any substance has been substituted wholly or in part; (3) if damage or inferiority has been concealed in any manner; or (4) 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.

III. Questions and Answers (Q & A)

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.

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 plants or secretions of living parts of plants and store in honeycombs."[2] FDA has concluded that this definition accurately reflects the common usage of the term "honey."

[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); "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, 2017, available at http://www.britannica.com/EBchecked/topic/270849/honey; and "Honey is the natural sweet substance produced by honey bees from the nectar of plants or from secretions of living parts of plants . . . ," CODEX Standard for Honey CODEX STAN 12-1981, available at: www.fao.org/input/download/standards/310/cxs_012e.pdf.

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

   If a food contains only honey, the food must be named "honey," which is its common or usual name (see section 403(i) of the FD&C Act and 21 CFR 101.3(b)). 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.

   (Please note that this answer pertains solely to how you name your product; other labeling requirements (e.g., net weight, nutrition facts) apply to the product. For more information, see FDA's Food Labeling Guide at https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm.)

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 you or the honey producer has information to support the conclusion that the plant or blossom designated on the label is the chief floral source of the honey. Names such as "Orange Blossom Honey," "Clover Honey," or "Wild Flower Honey" are acceptable. (See FDA Compliance Policy Guide, section 515.300.) Any claims about the floral source of the honey must be truthful and not misleading (see section 403(a)(1) of the FD&C Act).

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" because "[t]he common or usual name of a food . . . shall accurately identify or describe . . . the basic nature of the food or its characterizing properties or ingredients" (21 CFR 102.5(a)). Identifying a blend or a mixture of honey and another sweetener only as "honey" does not properly identify the basic nature of the food. 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**?

   For a food consisting of honey and a sweetener, the label must, among other information, include both of the following:

   a. A statement of identity, which must accurately identify or describe the basic nature of the food or its characterizing properties or ingredients (see section 403(i) of the FD&C Act, 21 CFR 101.3(b), and 21 CFR 102.5(a)): for example, "Blend of honey and corn syrup," if the food has more honey than corn syrup (conversely, "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 ingredient statement would show "honey" and the common or usual name of the sweetener (e.g., "sugar," "corn syrup"), in descending order of predominance by weight (see section 403(i) of the FD&C Act and 21 CFR 101.4(a)(1)).

You should also refer to section 403 of the FD&C Act and 21 CFR part 101, as other labeling requirements (e.g., net weight, nutrition facts) apply to your product. For more information, see FDA's Food Labeling Guide at https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm.

6. **If a food consists of honey and a flavor ingredient, such as natural raspberry flavor, what are the labeling requirements?**

a. If your labeling makes any direct or indirect representations with respect to the primary recognizable flavor (e.g., by word or vignette), other than through the statement of ingredients, the product is considered to have a characterizing flavor and must be labeled in accordance with 21 CFR 101.22(i). In such a case, you should choose a name that accurately describes the food with its characterizing flavor, such as "raspberry-flavored honey" (see section 403(i) of the FD&C Act, 21 CFR 101.3(b), and 21 CFR 102.5(a)).

b. In the statement of ingredients, the label must follow the requirements set forth in 21 CFR 101.4. The labeling must include the common or usual name of each ingredient in the ingredient statement. For a food consisting of honey and natural raspberry flavor, the ingredient statement would show "honey" and "natural flavor," in descending order of predominance by weight (see section 403(i) of the FD&C Act, 21 CFR 101.4(a)(1), and 21 CFR 101.22(h)(1)).

You should refer to section 403 of the FD&C Act and 21 CFR part 101, as other labeling requirements (e.g., net weight, nutrition facts) apply to your product. For more information, see FDA's Food Labeling Guide at https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm.

7. **How would consumers know whether the food is honey, a blend of honey and another sweetener (e.g., sugar or corn syrup), or a honey product that contains 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. By comparison, a properly labeled package of a blend of honey and a sweetener or other ingredients would have a statement of identity that accurately describes the food, such as "blend of honey and sugar," "blend of honey and corn syrup," or another appropriately descriptive term, and an ingredient statement that lists each ingredient, such as "honey" and "sugar," or "honey" and "corn syrup."

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 as one of the ingredients 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 solely 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, if there be any; 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, so "honey" is not an appropriate common or usual name under 21 CFR 102.5(a). Moreover, the ingredient statement lists only one ingredient, "honey," while the food contains "honey" and "natural flavoring." Therefore, the product fails to satisfy the requirements under 21 CFR 101.4(a)(1) and section 403(i)(2) of the FD&C Act, and FDA would consider such product to be 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, if any substance has been substituted wholly 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. Products that contain only honey and no other ingredients are considered more valuable than a food that contains both honey and sugar or both honey and corn syrup.[3] Therefore, we would consider such product adulterated under section 402(b)(1) of the FD&C Act because a valuable constituent (honey) has been omitted in part; under 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.

[3] Honey is more valuable than other sweeteners. See "Sugar and Sweeteners Yearbook Tables," United States Department of Agriculture Economic Research Service. 2017. Available at: https://www.ers.usda.gov/data-products/sugar-and-sweeteners-yearbook-tables.aspx.

Further, we would consider such food 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).

10. **How does FDA monitor imported products labeled as honey to ensure that they contain only honey as the sole ingredient?**

    We have a long-standing import alert for surveillance of honey for adulteration with cane or corn sugars (see Import Alert 36-01 at https://www.accessdata.fda.gov/cms_ia/importalert_108.html). Such a product would be detained until we determined that the product was not adulterated or misbranded.