



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 102

[Docket No. FDA-2019-D-0892]

The Use of an Alternate Name for Potassium Chloride in Food Labeling; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled “The Use of an Alternate Name for Potassium Chloride in Food Labeling.” The draft guidance, when finalized, will explain our intent to exercise enforcement discretion for the declaration of the name “potassium chloride salt,” as an alternative to “potassium chloride,” in the ingredient statement on the labels of foods that contain potassium chloride as an ingredient.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-D-0892 for "The Use of an Alternate Name for Potassium Chloride in Food Labeling." Received

comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Andrea Krause, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “The Use of an Alternate Name for Potassium Chloride in Food Labeling.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA 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 alternate approach if it satisfies the requirements of the applicable statutes and regulations. This draft guidance is not subject to Executive Order 12866.

This draft guidance, if finalized, is intended to explain to food manufacturers our intent to exercise enforcement discretion for the declaration of the name “potassium chloride salt” in the ingredient statement on food labels as an alternative to the common or usual name “potassium

chloride.” This flexibility in declaring potassium chloride in the ingredient statement on food labels may help inform consumers of the use of potassium chloride as at least a partial substitute for sodium chloride, thereby leading to the selection of foods with lower sodium content and decreasing the amount of sodium consumed. This draft guidance is consistent with FDA’s Nutrition Innovation Strategy (accessed at <https://www.fda.gov/food/labelingnutrition/ucm602651.htm>) to reduce the burden of chronic disease in the United States through improved nutrition, by empowering consumers with information, and supporting and fostering industry innovation in developing and promoting healthfulness of food options.

Americans consume, on average, 3,400 milligrams (mg) of sodium per day, nearly 50 percent more than the 2,300 mg/day limit recommended by the “2015-2020 Dietary Guidelines for Americans” (Ref. 1). Over 70 percent of sodium consumed comes from processed and prepared foods, which makes it difficult for consumers to control their sodium intake (Ref. 2). High levels of sodium intake are associated with increased blood pressure, which increases risk of cardiovascular disease (Refs. 3 to 6); researchers have estimated that reductions in sodium intake have the potential to prevent tens of thousands of premature deaths and illnesses each year (Ref. 7). Thus, associations between sodium intake and health outcomes support the need to engage in population-based efforts to lower excessive dietary sodium intakes. This draft guidance, when finalized, may facilitate development of lower sodium food options and is consistent with our previous actions to encourage stakeholders to reduce sodium levels in food products.

Sodium reduction techniques include the use of replacement ingredients to replicate the taste and preservative function of sodium chloride in foods. One such ingredient is potassium

chloride. Potassium chloride is an ingredient that is generally recognized as safe when used under conditions specified in our regulations at 21 CFR 184.1622. The food industry has used potassium chloride to reduce sodium chloride in prepared and processed foods. In most instances, potassium chloride is used as a partial substitute for sodium chloride. Adequate potassium intake is beneficial in lowering blood pressure, and potassium intake is generally low in comparison to Federal recommendations (Refs. 8 and 9).

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the label of a food fabricated from two or more ingredients must bear the common or usual name of each such ingredient (section 403(i)(2) of the FD&C Act (21 U.S.C. 343(i)(2))). A common or usual name is the name by which an article is known to the American public. Common or usual names are generally established by common usage, though in some cases they may be established by regulation. See 21 CFR 102.5(d). The common or usual name of potassium chloride has been established by common usage as “potassium chloride.”

The draft guidance takes into consideration a citizen petition from NuTek Food Science, dated June 27, 2016 (Docket No. FDA-2016-P-1826), requesting that we issue guidance recognizing “potassium salt” as an additional common or usual name for potassium chloride (Ref. 10). However, “potassium salt” is not a name in common usage for potassium chloride, and we are unaware of evidence that would support a regulation establishing “potassium salt” as the common or usual name.

In contrast, the name “potassium chloride salt” may signal to consumers that potassium chloride is a substitute for salt. Informing consumers that potassium chloride is a substitute for sodium chloride (salt) could result in consumers selecting food options with less sodium. This, in turn, could encourage industry to continue to reduce sodium levels in processed foods by

substituting potassium chloride for some sodium chloride, thereby decreasing overall sodium intake, increasing potassium intake, and benefitting public health. Because “potassium chloride salt” includes the entire common or usual name of the ingredient, we consider it unlikely that consumers will confuse it with sodium chloride or other potassium-containing salts. Therefore, we tentatively intend to exercise enforcement discretion for the declaration of “potassium chloride salt” in the place of “potassium chloride” in the ingredient statement on labels of foods containing potassium chloride as an ingredient.

II. Other Issues for Consideration and Request for Information

We will review any consumer data and other information that is submitted to us to determine whether “potassium chloride salt” has become an alternate common or usual name for potassium chloride in the future.

We invite comment on the following questions. Please provide the reasoning behind your comments, including, where available, any data or other supporting information.

1. How would use of the name “potassium chloride salt” in the ingredient statement as an alternative to “potassium chloride” improve consumer understanding of this ingredient? What other methods or approaches could improve consumer understanding? Please provide any relevant data or information to support your answer.

2. What alternate names to “potassium chloride salt” would better promote consumer understanding of potassium chloride? Please provide any relevant data or information to support your answer.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. U.S. Department of Health and Human Services and U.S. Department of Agriculture, “2015--2020 Dietary Guidelines for Americans,” 8th Ed., December 2015. <http://health.gov/dietaryguidelines/2015/guidelines/>, accessed December 10, 2018.*
2. Harnack, L.J., M.E. Cogswell, J.M. Shikany, et al., “Sources of Sodium in US Adults From 3 Geographic Regions.” *Circulation*, 135:1775-1783, 2017.
3. Institute of Medicine, “Dietary Reference Intakes for Water, Potassium, Sodium Chloride and Sulfate.” Washington DC: The National Academies Press. 2005.
4. Sacks, F.M., L.P. Svetkey, W.M. Vollmer, et al., “Effects on Blood Pressure of Reduced Dietary Sodium and the Dietary Approaches to Stop Hypertension (DASH) diet.” DASH--Sodium Collaborative Research Group. *New England Journal of Medicine*, 344(1): 3-10, 2001.

5. Graudal, N.A., T. Hubeck-Graudal, and G. Jürgens, “Effects of Low-Sodium Diet vs. High-Sodium Diet on Blood Pressure, Renin, Aldosterone, Catecholamines, Cholesterol, and Triglyceride (Cochrane Review).” *American Journal of Hypertension*, 25(1):1-15, 2012. PMID: 22068710. <http://www.ncbi.nlm.nih.gov/pubmed/22068710>, accessed December 10, 2018.

6. Eckel, R.H., J.M. Jakicic, J.D. Ard, et al., “2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.” *Journal of the American College of Cardiology*, 63(25 Pt B):2960-2984, 2014. PMID: 24239922. <http://www.ncbi.nlm.nih.gov/pubmed/24239922>, accessed December 10, 2018.

7. Coxson, P.G., N.R. Cook, M. Joffres, et al., “Mortality Benefits From US Population-wide Reduction in Sodium Consumption: Projections from 3 Modeling Approaches.” *Hypertension*, 61:564-570, 2013.

8. U.S. Department of Agriculture and U.S. Department of Health and Human Services. “Scientific Report of the 2015 Dietary Guidelines Advisory Committee,” Part B, Chapter 6. <http://www.health.gov/dietaryguidelines/2015-scientific-report/>, accessed December 10, 2018.*

9. Jackson, S.L., M.E. Cogswell, L. Zhao, et al., “Association Between Urinary Sodium and Potassium Excretion and Blood Pressure Among Adults in the United States: National Health and Nutrition Examination Survey, 2014.” *Circulation*, 137:237-246, 2018.

10. Petition from Brian L. Boor, President and Chief Operating Officer, NuTek Food Science, LLC, to Division of Dockets Management, Food and Drug Administration, Docket No. FDA-2016-P-1826, dated June 27, 2016.*

Dated: May 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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