



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; 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 final guidance for industry entitled “The Use of an Alternate Name for Potassium Chloride in Food Labeling.” This guidance explains our intent to exercise enforcement discretion for the declaration of the name “potassium salt,” as an alternative to “potassium chloride,” in the ingredient statement on the labels of foods that contain potassium chloride as an ingredient.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on FDA guidances 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

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 guidance for industry entitled “The Use of an Alternate Name for Potassium Chloride in Food Labeling.” We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents 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 alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the *Federal Register* of May 20, 2019 (84 FR 22749), we made available a draft guidance for industry entitled “The Use of an Alternate Name for Potassium Chloride in Food Labeling” (“draft guidance”), which was 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.” The draft guidance considered, in part, a NuTek Food Science citizen petition requesting that we issue guidance recognizing “potassium salt” as an additional common or usual name for potassium chloride (see Citizen Petition from NuTek Food Science, LLC, dated June 27, 2016, FDA-2016-P-1826-0001 at page 1). Additionally, we specifically invited comment on how the use of the name “potassium chloride salt” in the ingredient statement as an alternative to “potassium chloride” would improve consumer understanding of the ingredient and what alternate names to “potassium chloride salt” would better promote consumer understanding of potassium chloride (84 FR 22749 at 22750 through 22751). We gave interested parties until July 19, 2019, to submit comments for us to consider before beginning work on the final version of the guidance.

In response to requests for more time to comment on the draft guidance, we issued a notice in the *Federal Register* of July 10, 2019 (84 FR 32848) extending the comment period to September 17, 2019. We received more than 70 comments on the draft guidance. Many comments expressed concerns that declaration of the alternate name “potassium chloride salt” would be confusing or would not achieve the public health goal of reduced sodium consumption,

as food manufacturers would likely not use the alternate name. Food manufacturers, public health and consumer advocacy groups provided comments and data supporting “potassium salt” as an alternate name to “potassium chloride.”

After careful review and consideration of the comments to the draft guidance, some of which led us to further review of relevant published literature, we have modified the final guidance. Changes to the guidance include:

- Exercising enforcement discretion for declaration of “potassium salt,” rather than “potassium chloride salt,” in the ingredient statement on food labels as an alternative to declaration of the common or usual name “potassium chloride;” and
- Further explaining potassium chloride’s technical role as a partial substitute for sodium chloride in food manufacturing through the inclusion of additional examples and references.

As discussed in the final guidance, we have made these changes with the following considerations in mind: potential public health benefits to the U.S. population from reduced sodium and increased potassium intake, the recognition that potassium chloride can substitute for sodium chloride in a variety of food manufacturing applications across a number of food categories, and the unlikelihood that the alternate name will mislead consumers.

The guidance announced in this notice finalizes the draft guidance dated May 2019.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910-0381.

III. Electronic Access

Persons with access to the internet may obtain the 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.

Dated: December 11, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-27750 Filed: 12/17/2020 8:45 am; Publication Date: 12/18/2020]