



January 17, 2023

Mr. Nathan A. Brown  
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2001 K Street, N.W.  
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Via email: [nabrown@akingump.com](mailto:nabrown@akingump.com)

Re: Docket No. FDA-2022-P-1668

Dear Mr. Brown:

This letter is in response to your citizen petition (FDA-2022-P-1668) dated July 22, 2022, requesting the Food and Drug Administration to “amend the standard of identity for Pasteurized Orange Juice to reduce the minimum Brix level.”

The exact amendment requested is as follows, with proposed additions indicated in bold and underlined and proposed deletions indicated with strikethrough:

**Amendment to 21 C.F.R. § 146.140 - Pasteurized orange juice.**

(a) Pasteurized orange juice is the food prepared from unfermented juice obtained from mature oranges as specified in § 146.135, to which may be added not more than 10 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids (except that this limitation shall not apply to the hybrid species described in § 146.135). Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) are removed, and pulp and orange oil may be adjusted in accordance with good manufacturing practice. If the adjustment involves the addition of pulp, then such pulp shall not be of the washed or spent type. The solids may be adjusted by the addition of one or more of the optional concentrated orange juice ingredients specified in paragraph (b) of this section. One or more of the optional sweetening ingredients listed in paragraph (c) of this section may be added in a quantity reasonably necessary to raise the Brix or the Brix-acid ratio to any point within the normal range usually found in unfermented juice obtained from mature oranges as specified in § 146.135. The orange juice is so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms. Either before or after such heat treatment, all or a part of the product may be frozen. The finished pasteurized orange juice contains not less than ~~10.5~~ **10.0** percent by weight of orange juice soluble solids, exclusive of the solids

U.S. Food and Drug Administration  
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of any added optional sweetening ingredients, and the ratio of the Brix hydrometer reading to the grams of anhydrous citric acid per 100 milliliters of juice is not less than 10 to 1.

In accordance with Title 21 Code of Federal Regulations, section 10.30(e)(2), this letter is to advise you that we were not able to reach a decision on your petition within the first 180 days of its receipt, nor as of the date of this letter. When we complete our review of your petition, we will notify you of our decision. If you have any questions, please contact us.

Sincerely,

Claudine Kavanaugh, Ph.D., MPH, RD  
Director  
Office of Nutrition  
and Food Labeling  
Center for Food Safety  
and Applied Safety