CITIZEN PETITION

SUBJECT OF PETITION:

Request to Amend Pasteurized Orange Juice Standard of Identity

(21 C.F.R. § 146.140)

PETITIONERS:

Florida Citrus Processors Association Inc.

Florida Citrus Mutual Inc.

SUBMITTED VIA ELECTRONIC FILING TO:

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane,
Rockville, MD 20852

CITIZEN PETITION CONTACT:

Nathan A. Brown
Akin Gump Strauss Hauer & Feld LLP
Robert S. Strauss Tower
2001 K Street, N.W.
Washington, DC 20006
(W) (202) 887-4245
(Fax) (202) 887-4288
nabrown@akingump.com

DATE: July 22, 2022

CITIZEN PETITION

The Florida Citrus Processors Association and Florida Citrus Mutual (hereafter, Petitioners)[1] submit this petition under Sections 401 and 701(e) of the Federal Food, Drug, and Cosmetic Act (FDCA) to request the Commissioner of the Food and Drug Administration (FDA) amend the standard of identity for Pasteurized Orange Juice (21 C.F.R. § 146.140) as set forth below.

I. ACTION REQUESTED.

The Petitioners request that FDA 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 that 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 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.

[1] *See* Descriptions of Petitioners Florida Citrus Processors Association and Florida Citrus Mutual (**Appendix 1**).

II. STATEMENT OF GROUNDS.

a. History of the Standard.

FDA created the Pasteurized Orange Juice standard of identity in 1963, along with other orange juice standards, with input from stakeholders, including extensive agency engagement and fact finding.[2] The proposed standards were first published in 1956.[3] These standards are intended to protect the interests of consumers and to reflect consumer expectations regarding orange juice. FDA's standard has generally established Pasteurized Orange Juice as a high quality and minimally processed juice that is heat-treated to eliminate potentially harmful pathogens, and that is not concentrated or reconstituted with added water.

The Pasteurized Orange Juice standard set specific requirements for juice content and labeling, including a minimum fruit sugar level. When FDA promulgated this standard, the agency recognized that Florida was the dominant supplier of juice oranges (a status Florida has continued to hold), with the agency noting that the Florida orange crop had an average Brix of 11.8° at that time.[4] Based on the fruit used in preparing pasteurized orange juice at the time, FDA set a minimum Brix value of 10.5° for the Pasteurized Orange Juice standard. Notably, there was nothing inherently superior about the Brix level identified in the rulemaking.

b. Modernization.

1. Reduce the minimum Brix value for pasteurized orange juice to 10° Brix.

Since 2005, Florida's orange trees have been increasingly infected by *Huanglongbing* (HLB or citrus greening disease). FDA has recognized the substantial impact of this disease, explaining that "the recent 'orange greening' scourge in Florida has affected nearly every orange grove in the state, which directly impacts crop yields and, subsequently, prices of commodities."[5] Similarly, the U.S. Department of Agriculture (USDA) has identified HLB as "one of the most serious citrus plant diseases in the world" and "devastating to the Florida citrus industry and severely threatens citrus production in other parts of the United States."[6] Florida's citrus crops have also been subject to substantial severe weather in recent years, most notably Hurricane Irma

[2] *See* Orange Juice and Orange Juice Products; Definitions and Standards of Identity; Findings of Fact and Final Order, 28 Fed. Reg. 10,900 (Oct. 11, 1963) (**Appendix 2**); 21 C.F.R. §§ 146.135 146.140, 146.141, 146.146, 146.151, 146.137, 146.145, 146.148, 146.150, & 146.154.

[3] Notice of Proposals to Establish Definitions and Standards of Identity for Certain Types of Orange Juice, 21 Fed. Reg. 8,511 (Nov. 6, 1956).

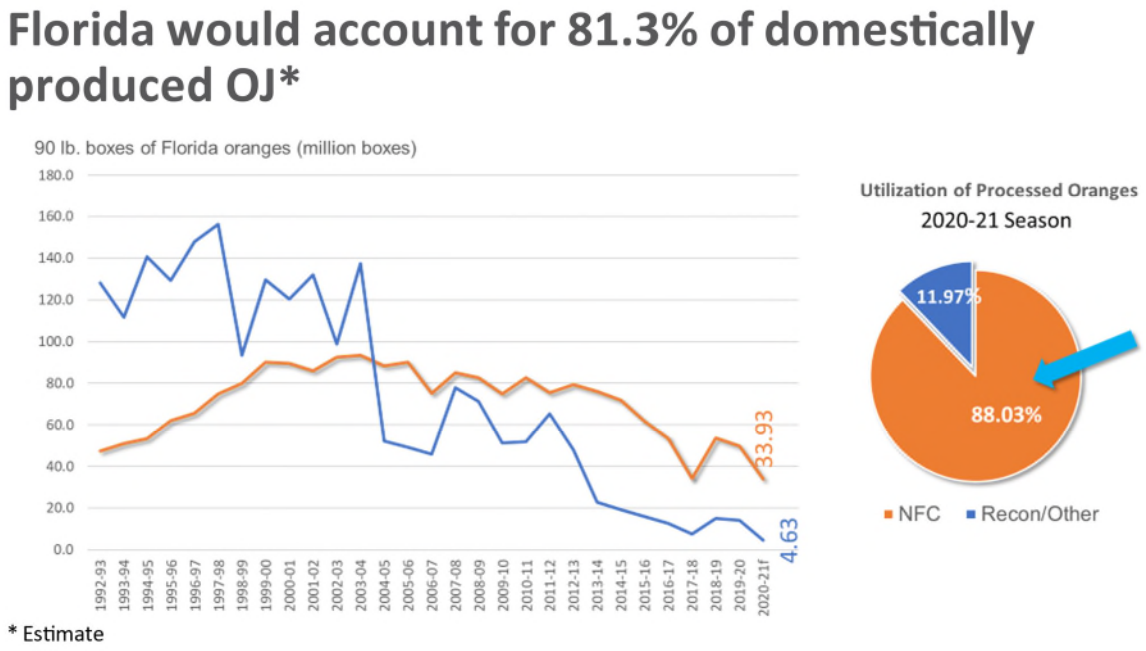
[4] 28 Fed. Reg. 10,905 ("The approximate average of the soluble solids in the Florida orange juices available for processing is 11.8° Brix.") (**Appendix 2**).

[5] FDA, Final Environmental Impact Statement (EIS) for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Oct. 2015) at 103, https://www.fda.gov/files/food/published/FINAL-Environmental-Impact-Statement-%28EIS%29-for-the-FSMA-Proposed-Rule-for-Produce-Safety.pdf.

[6] USDA, Animal and Plant Health Inspection Service, Citrus Greening, https://www.aphis.usda.gov/aphis/resources/pests-diseases/hungry-pests/the-threat/citrus-greening/citrus-greening-hp (last visited July 2022); USDA, Agricultural Research Service, Combating Citrus Greening Disease (May 29, 2020), https://www.ars.usda.gov/research/annual-report-on-science-accomplishments/fy-2019/combating-citrus-greening-disease/

in 2017, which has also damaged Florida's orange groves, further reducing production of oranges and normal fruit sugar content.[7] As a result, Florida's average Brix level has steadily dropped from 12.6° in the 2010-11 orange season to 10.5° in the 2020-21 season.

Experts do not expect the average Brix level to return to previous averages without resolution of HLB, which remains incurable. While California's orange crops are primarily produced for the fresh market, citrus processors use almost the entire Florida orange crop for the production of "not from concentrate" (NFC) pasteurized orange juice. This utilization makes it critical for FDA to establish a minimum requirement of 10.0° Brix instead of 10.5° Brix for pasteurized orange juice, to reflect Florida's mature orange Brix values.



Data Source: Florida Department of Citrus

Due to tree stress caused by weather and disease pressures, particularly HLB, Florida's oranges have not achieved an average of 11.8° Brix since the 2013-14 season. Season average Brix values (weighted by volume) are today hovering below the minimum of 10.5° Brix.[8] As of the date of this petition, the current season's (2021-2022) Brix values shown in the chart below and derived from all oranges processed in the State of Florida by the Florida Department of Agriculture and Consumer Services, are at 10.0° Brix and well below the FDA minimum Brix for pasteurized orange juice.[9]

[7] *See* USDA, Economic Research Service, Hurricane Irma Hits Florida's Agricultural Sector (Feb. 5, 2018), https://www.ers.usda.gov/amber-waves/2018/januaryfebruary/hurricane-irma-hits-florida-s-agricultural-sector/.
[8] Florida Department of Agriculture and Consumer Services, Historic Brix Tables (**Appendix 3**).
[9] *See id*.

2021-2022 Season	
Month	**Average Brix**
October (2021)	10.09
November (2021)	9.47
December (2021)	9.69
January (2022)	10.21
February (2022)	9.86
March (2022)	9.9
April (2022)	10.12
May (2022)	10.41
YTD Average	**10.00**
Data Source: Florida Department of Agriculture and Consumer Services; Division of Fruit and Vegetable, Statistics from State Test House Data through 2021-22 Season YTD (weighted average)	

Consumers widely understand pasteurized orange juice to be natural NFC juice made from mature Florida oranges. The FDA's pasteurized orange juice standard of identity, when originally promulgated in 1963, was carefully constructed to reflect the qualities of U.S. oranges. It should now be updated to align with the properties of the modern U.S. crop. Without these changes, manufacturers of finished pasteurized orange juice products must increasingly rely on higher Brix imported juice to meet or exceed the U.S. *minimum* Brix for pasteurized orange juice.

Given that standards of identity are intended to serve the interests of consumers, FDA may question whether consumers will find less sweet juice acceptable. Notably, NFC, which has been the most popular orange juice form, has not included the addition of concentrate for adjustment of Brix for at least 20 years. In recent correspondence with Florida Citrus Mutual regarding a lower minimum Brix for pasteurized orange juice, FDA inquired about the potential impact on consumers of such juice made with lower Brix oranges. We are confident that any orange juice products with lower Brix will be appropriately processed and blended to reflect consumer preferences and be further refined based on any consumer feedback. Furthermore, there are no health benefits to consumers in having fruit sugar content enhanced beyond the natural level in mature oranges.

Each orange juice brand/manufacturer will have their own proprietary blending formulations, methods, and processes to prepare and finish juice products (e.g., varietal blending, removal of bitter components, restoring aromas/oils). Because of the standard in place, finished products below the current minimum Brix standard do not exist, so Petitioners have no market tested commercial product to share with FDA. Should Brix levels bounce back up, the minimum will not be an issue because the juice will be packed to the naturally occurring Brix levels in the crop.

Temporary marketing permits for lower Brix product would not be a viable option to employ in lieu of a standard change, due to the overwhelming prevalence of low Brix across the domestic juice orange crops over multiple seasons, and FDA's requirements to distinguish any lower Brix

juice packed under permit from the standardized 10.5° Brix product and bear different labeling. Multiple labels and added SKUs for essentially the same product would create unnecessary burden for manufacturers and would be confusing to consumers, making such an outcome both undesirable and difficult for manufacturers and consumers.

However, key takeaways from a recent industry consumer survey show that 96% of the consumers in the study accepted the idea that a natural product, like orange juice, could have varying levels of sweetness.[10] 95% of those surveyed agreed that orange juice with less sugar should still be called orange juice and 76% claimed that they would have no concerns with a less sweet orange juice.[11]

Consumers make choices based on their individual preferences for orange juice, and it is the realm of manufacturers to offer products that meet the taste and flavor expectations of their consumers. A single analyte, such as a Brix value of the packaged product, does not dictate great tasting orange juice. There are other components that make up flavor. There has been an explosion of juice and beverage choices for consumers, many fortified, since FDA's orange juice standards were adopted in 1963. If lower Brix juice made from mature oranges does not taste good, it will not last very long on the market and Brix in finished product will, as now, be elevated using juice from multiple production areas.

The 10.0° Brix level in the amendment is consistent with the minimum Brix level of 10.0° in FDA's standard of identity for canned orange juice.[12] Further, it would be consistent with the applicable Codex General Standard for Juices and Nectars, which has no minimum but allows for Brix for not-from-concentrate pasteurized orange juice to be at the Brix level of the fruit from which the juice is directly expressed.[13] The European Fruit Juice Directive incorporates a minimum Brix of 10.0° Brix, established by the European Fruit Juice industry in the AIJN Code of Practice.[14]

2. Harmonization.

Petitioners are aware that some aspects of this petition are relevant to FDA's horizontal review of all standards of identity and highlight previous comments submitted by Florida Citrus Processors Association consistent with those in this petition in Docket # FDA-2018-N-2381.[15]

Petitioners remain supportive of FDA's efforts to modernize U.S. food standards by aligning with international standards to the extent practicable, and providing additional flexibilities and opportunities for innovation. As highlighted above, this proposed minimum Brix decrease would

[10] Target Research Group, Orange Juice Consumer Survey; Orange Juice and Sugar Content (Dec. 15, 2021) (**Appendix 4**).
[11] *Id.*
[12] *See* 21 C.F.R. § 146.141.
[13] Codex Alimentarius Commission, General Standard for Fruit Juices and Nectars (Codex Stan 247-2005) at § 3.1.1(a) (**Appendix 5**).
[14] AIJN-European Fruit Juice Association, Code of Practice; Reference Guideline for Orange Juice (Sept. 2019) (**Appendix 6**).
[15] Florida Citrus Processors Association, Comment Letter re Horizontal Approaches to Food Standards (Nov. 10, 2019, https://downloads.regulations.gov/FDA-2018-N-2381-1388/attachment_1.pdf (**Appendix 7**).

help to bring the pasteurized orange juice standard into alignment with certain international food standards, supporting FDA's broader harmonization goals. However, for the reasons detailed in this Petition, U.S. citrus growers and orange juice consumers require urgent and targeted FDA action on the Pasteurized Orange Juice standard.

c. Pasteurized Orange Juice Competes With Fruit Juices Having No U.S. Standards of Identity.

Most fruit juices, albeit many of which are relatively lower by volume of sales, have *no U.S. standard of identity*. While we are not requesting that these competitors be subject to a standard of identify, this regulatory discrepancy further emphasizes the need to amend the orange juice standard of identity to keep pace with modern scientific understanding and naturally occurring dynamics impacting product production. Without such an update, Petitioners' pasteurized orange juice products will be further disadvantaged in the market. Fruits with standards in the Codex General Standard for Fruit Juices and Nectars (Codex Stan 247-2005) but without U.S. juice standards are listed below by their common names:

> Kiwi, cashew apple, soursop, sugar apple, carambola, papaya, star apple, water melon, lime, sour orange, Mandarin tangerine, coconut melon, casaba melon, honeydew melon, quince, persimmon, crowberry, loquat, guava berry birch berry, Suriname cherry, fig, kumquat, strawberry, "Genipap," sea buckthorn, buckthorn berry, litchi/lychee, acer, acerola, apple, mammee apple, mango, banana, yellow passion fruit, passion fruit, date, sapote, apricot, sweet cherry, sour cherry, stonesbaer, plum, quetsche, nectarine, peach, sloe, guava, pomegranate, Aronia, pear, black currant, red currant , white currant, red gooseberry, white gooseberry, cynorrhodon, rosehip, cloudberry, mulberry, blackberry, dewberry, red raspberry, loganberry, black raspberry, boysenberry, youngberry, elderberry, "Lulo," rowanberry, sorb, "Caja," "Umbu," pome apple, tamarind, cocoa pulp, "Cupuacu," cranberry, bilberry, blueberry, lingonberry, grape.[16]

d. Conclusion.

In conclusion, the Petitioners strongly believe that this proposed change to the Pasteurized Orange Juice standard of identity is necessary, warranted, and overdue. This proposed change would be consistent with consumer expectations for pasteurized orange juice, which is widely understood to be natural NFC juice made from mature Florida oranges. Furthermore, this decrease to the Brix minimum would help to bring the pasteurized orange juice standard into alignment with the existing properties of the mature oranges used for juice production, as well as certain international food standards. Finally, there are no adverse health consequences for consumers, and there may even be health benefits.

[16] Codex Alimentarius Commission, General Standard for Fruit Juices and Nectars (Codex Stan 247-2005) (**Appendix 6**).

III. ENVIRONMENTAL IMPACT ASSESSMENT.

Petitioners claim a categorical exclusion from the requirement of an Environmental Impact Statement in relation to an amendment of a food standard pursuant to 21 C.F.R. § 25.32 (a).

IV. ECONOMIC IMPACT.

A statement of economic impact will be provided to the extent requested by the Commissioner of Food and Drugs.

V. CERTIFICATION.

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition.

Respectfully Submitted,

FLORIDA CITRUS PROCESSORS ASSOCIATION INC.

Kristen Carlson
Executive Director
201 North Franklin Street, Suite 2000
Tampa, FL 33602

FLORIDA CITRUS MUTUAL INC.

G. Mathew Joyner
Executive Vice President/CEO
600 N. Broadway Avenue, Suite 101
Bartow, FL 33830

Contact for Citizen Petition:
Nathan A. Brown
Akin Gump Strauss Hauer & Feld LLP
Robert S. Strauss Tower
2001 K Street, N.W.
Washington, DC 20006
(W) (202) 887-4245
(Fax) (202) 887-4288
nabrown@akingump.com

LIST OF APPENDICES