SUBJECT:  Fortification of Standardized Juices

TO:  All Inspectors

FILE UNDER:  Citrus Manual:  Section 3, Parts 1 and 2, Food and Drug Standards

Commodity Folders:  Standardized Fruit Juices, Concentrated and Single Strength

PURPOSE

To clarify grading procedures when a standardized fruit juice product is subject to mineral or vitamin fortification, and the Food and Drug Administration (FDA) Standards of Identity may or may not include such enrichment or fortification as an optional ingredient.

PROCEDURE

When FDA’s Standards of Identity for fruit juices, 21 CFR Part 146, have no provision for mineral or vitamin fortification (optional ingredients), then any addition of such ingredients beyond a level which is normally expected for the product changes the product characteristics. This prohibits the end item from being considered under the product’s original Standards of Identity. Therefore, the finished product is evaluated as a No Applicable Grade (NAG) item, using appropriate descriptive terms to record the level of quality. The applicant has the responsibility to ensure product labels bear the correct information in accordance with FDA’s “Generic Standard,” 21 CFR 130.10.

When FDA Standards of Identity of a finished product or the concentrates used to produce such product allows for the addition of a vitamin or (fortifier), then the U.S. Standards for Grades is applicable and a U.S. Grade is assigned.
EXAMPLE:

Orange juice from concentrate $146.145, of 21 CFR Part 146, may be produced from the standardized products of $146.146, $146.153, $146.135, $146.137, $146.140, and/or $146.151. FDA prohibits the addition of a vitamin in any of these products. Should a vitamin be added, the U.S. Standards for Grades is not applicable, and the orange juice from concentrate is evaluated as a NAG item.

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