

APPENDIX D

Item 232-3: Handbook 130, Method of Sale Regulation

Section 1.7.1. Factory Packaged Ice Cream and Similar Frozen Products

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

AUG 02 2010

Cary Frye
Vice President
Regulatory Affairs
International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association
1250 H Street NW, Suite 900
Washington, DC 20005

Dear Ms. Frye:

This is in response to your April 2 and May 14, 2010 letters to the Food and Drug Administration (FDA) seeking FDA's position on the appropriate net quantity of contents declarations for pelletized frozen desserts, other than ice creams. You requested FDA's confirmation on its position prior to the National Conference on Weights and Measures meeting to be held on July 11, 2010 so that the regulations on the method of sale may be appropriately amended at this meeting.

You stated in your letter that FDA clarified its position in the April 17, 2009 letter to the International Ice Cream Association (IICA) that net quantity of contents statements for pelletized ice creams should be expressed in terms of weight, not volume. You also stated that IICA believes that it is reasonable to assume that the same rationale that led FDA to this determination would support a position that labels of other pelletized frozen desserts should also include declarations expressed in terms of weight.

In a letter dated April 17, 2009 to IICA, FDA concluded that pelletized ice cream is a unique and totally new ice cream product that has emerged in the market place and because it is a semisolid food, and in accordance with 21 CFR 101.105(a), the net quantity of content declaration for this type of product would be net weight. In addition, FDA concluded that since there is not a firmly established general consumer usage and trade custom of expressing the quantity of contents declaration in terms of volume on pelletized ice cream, net weight would be appropriate.

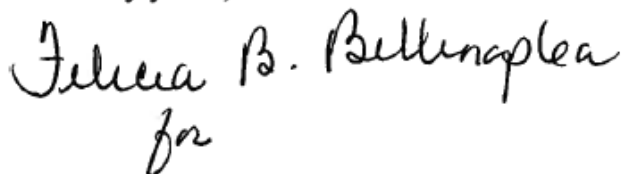
Like pelletized ice cream, other similar pelletized frozen desserts are unique and new frozen desserts that are emerging in the marketplace. Because they are semisolid foods, in accordance with 21 CFR 101.105(a), and consistent with the net quantity for pelletized ice cream, the appropriate net quantity of content declaration for these products would be net weight. In addition, there is not a firmly established general consumer usage and trade custom of expressing the quantity of contents declaration in terms of volume on other similar pelletized frozen desserts.

As you stated, pelletized frozen desserts are manufactured at very low temperatures using a nitrogen process and consists of thousands of small beads of water ice, sherbet or other frozen desserts of varying sizes that are quick frozen. Moreover, because there is variation in the diameter of the pieces, settling in the package, and the absence of a test procedure, FDA believes that a net quantity of content declaration using a volume measurement would be difficult for manufacturers to determine and confirm and for regulatory officials to test.

FDA believes that a net weight approach would eliminate the need to develop a new test procedure that could be time consuming and require expensive test equipment. It appears that because of the uniqueness of these products, a net weight declaration would be an easier measurement to test than a volume declaration. Therefore, FDA believes that the net quantity of content statement on pelletized frozen desserts, in addition to pelletized ice cream, that conform to the standards for frozen desserts in 21 CFR part 135 and nonstandardized frozen desserts that are similar to the standardized frozen desserts in 21 CFR part 135 should be declared in terms of net weight. We would expect manufacturers of these pelletized frozen desserts to revise their labels to reflect a net weight declaration during the next printing cycle and encourage all marketers of pelletized frozen desserts to modify their labels with a net weight declaration within one year from the issue date of this letter.

If you have additional questions, do not hesitate to contact us.

Sincerely yours,

Handwritten signature of Juliana B. Bellinoplea in cursive script, with the word "for" written below it.

Geraldine A. June
Supervisor
Product Evaluation and Labeling Team
Office of Nutrition, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition