

Appendix H

Letter Submitted from the International Ice Cream Association to the Food and Drug Administration

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July 10, 2008

Ms. Geraldine A. June
Team Leader, Food Labeling and Standards
Office of Nutritional Products, Labeling and Dietary Supplements
FDA/Center for Food Safety & Applied Nutrition
CPK1/4D014
5100 Paint Branch Parkway
College Park, MD 20740
Sent Via E-mail to: geraldine.june@cfsan.fda.gov

RE: Request for Interpretation of FDA Food Labeling Regulations for Net Quantity of Contents and Serving Size of Pelletized Ice Cream and Frozen Desserts

Dear Ms. June:

The International Ice Cream Association (IICA) appreciated the opportunity to meet on June 27, 2008 with officials from FDA's Office of Food Labeling, along with staff from the National Institute of Standards and Technology (NIST) Weights and Measure's Division, and regional Weights & Measures officials to discuss the net contents declaration and method of measurement for pelletized ice cream.

We are writing this letter seeking FDA assistance on determining the net quantity of content statement and serving size declaration that should be used for pelletized ice cream and frozen desserts. For the reasons noted below, IICA believes the net quantity of content statement should be a volumetric declaration that excludes the external air. We also are asking for FDA guidance in identifying the serving size that should appear in the nutrition facts panel for these products.

Pelletized ice cream is a unique and novel ice cream product that entered the market in 1988 under the brand name Dippin' Dots,™ which was predominantly sold in food service venues to consumers for immediate consumption. Due to commercialization and development of processing technology, pelletized ice cream has been introduced into retail stores over the past several years by five companies. Today the product is sold in food service and retail stores both in multi-serving and individual serving packages.

Pelletized ice cream products meet the federal standard of identity (SOI) for ice cream as specified in 21 CFR §135.110. The product is made using pasteurized mix consisting of one or more of the prescribed dairy ingredients, sweeteners, stabilizers and flavorings. The ice cream

mix is stirred via pumping and spraying action as the droplets are frozen at very low temperatures using liquid nitrogen. The freezing process results in small round shaped beads or pellets of ice cream that meet the required 4.5 lbs per gallon weight requirements set forth in the SOI for ice cream. Different flavored ice cream pellets such as strawberry, banana, chocolate and vanilla may be mixed together to create novel flavors such as "banana split," or flavoring can be added to the pellets such as cookie pieces, cookie dough, brownies, and other inclusions. In addition to pelletized ice cream, this same freezing process is also used to produce similar products such as pelletized water ice and pelletized frozen desserts. IICA believes that determination of the method of sale and serving size in the nutrition fact panel should apply to all pelletized ice cream, and all pelletized frozen dessert products.

As we discussed during the June 27th meeting, ice cream and frozen desserts are sold by units of fluid measure. Therefore, the declared net quantity of contents for pelletized ice cream and frozen desserts will be expressed in fluid ounces. The ice cream industry's position is that the method of sale and net quantity of contents for pelletized ice cream and pelletized frozen desserts should be declared in fluid ounces without including any external air surrounding the pellets of ice cream or flavoring. We are seeking concurrence from FDA that it agrees with the industry position of using in the net quantity statement fluid ounces that exclude the external air.

We also are seeking FDA guidance on the serving size that should be stated in the nutrition facts panel (NFP) for pelletized ice creams and frozen desserts. During the June 27th meeting we discussed the issue and are asking FDA to identify the serving size that should be used on these products.

We would greatly appreciate your prompt reply in this matter, as it is critical to future work on determining the proper method for measuring the volume of the pelletized ice cream and frozen desserts. The IICA would like to propose a new method of measurement for this product to the 2009 National Conference of Weights and Measures. In order to meet that deadline we would need to develop and verify a test method to submit the proposal to the Southern Weights and Measures Association meeting on October 5, 2008.

If you have any questions or require additional information regarding this matter, please feel free to contact me at (202) 220-3543 or via e-mail at cfrye@idfa.org.

Sincerely,



Cary Frye
Vice President,
Regulatory Affairs

cc: K. Butcher, NIST
L. Warfield, NIST