

Appendix I

FDA Decision on Pelletized Ice Cream

(Letter Dated April 17, 2009)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR 17 2009

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 July 10, 2008 letter to the Food and Drug Administration (FDA) and a follow up to the June 27th meeting at the National Institute of Standards and Technology (NIST) seeking assistance on how to determine the appropriate net quantity of content statement for pelletized ice cream and the appropriate measurement, i.e. volume excluding the external air versus net weight. You also asked FDA for clarification on the appropriate serving size for these products.

You stated in your letter that the International Ice Cream Association believes the net quantity of content statement for pelletized ice cream and frozen desserts should be a volumetric declaration that excludes the external air. You stated that, as we discussed at the June 27th meeting at NIST, ice cream and frozen desserts are sold by units of fluid measure and, therefore, the declared net quantity of contents for pelletized ice cream and frozen desserts should be expressed in fluid ounces. Further, you stated that the ice cream industry's position is that the method of sale and the net quantity of contents for pelletized ice cream be declared in fluid ounces without any external air surrounding the pellets of ice cream or flavoring.

By way of background, the FDA enforces the Federal Food, Drug, and Cosmetic Act (FFDCA) and certain provisions of the Fair Packaging and Labeling Act (FPLA). The FFDCA requires that all labeling and packaging of food products, including the net quantity of contents statement, be truthful, informative, and not deceptive. The FPLA is concerned with the labeling of packaged consumer goods for retail sale to enable consumers to obtain accurate information about the quantity of contents and to facilitate value comparisons. Compliance with these laws and the regulations promulgated under the authority of these laws is secured through periodic inspections of facilities and products, analyses of samples, educational activities, investigations of consumer trade complaints, and legal proceedings.

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Provisions of 21 CFR 101.105(a) specify that the declaration of quantity of contents shall be in terms of weight if the product is solid, semisolid, or viscous, or a mixture of solid and liquid. Thus, it would appear that traditional ice cream products, being semisolid foods, would be declared by weight. However, provisions of §101.105(a) also provide that if there is a firmly established general consumer usage and trade custom of declaring the contents of a liquid by weight, or a solid, semisolid, or viscous product by fluid measure, it may be used. Because there appears to be a firmly established general consumer usage and trade custom of expressing quantity of contents declarations on traditional ice cream products in terms of volume, the agency has not required industry to revise their declarations to be expressed in terms of weight.

Pelletized ice cream is a unique and totally new ice cream product that is emerging in the marketplace. Because it is a semisolid food, in accordance with 21 CFR 101.105(a), 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 pelletized ice cream.

As you know, pelletized ice cream is manufactured at very low temperatures using a nitrogen process and consists of thousands of small beads of ice cream of varying sizes. 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. In addition, density variations occur when inclusions are added to packages of pelletized ice cream. Because these inclusions such as cookie bits, themselves, vary in size and weight, using gravimetric testing to verify the declared volume of a sample may not be practical.

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. Furthermore, it is FDA's understanding that these products have been sold by net weight from at least one manufacturer in the United States for more than a year and there is no record of any consumer complaints regarding the method of sale. Therefore, FDA believes that the net quantity of content statement on pelletized ice cream should be declared in terms of net weight. We would expect manufacturers of pelletized ice cream to revise their labels to reflect a net weight declaration during the next printing cycle and encourage all marketers of pelletized cream to modify their labels with a net weight declaration within one year from the issue date of this letter.

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With regards to your request for guidance in identifying the serving size that should appear in the nutrition facts panel for pelletized ice cream, we point out that FDA regulations in 21 CFR 101.12 establish reference amounts customarily consumed and how to use these reference amounts to declare serving sizes. In 21 CFR 101.12(b), Table 2, the reference amount for ice cream, ice milk, frozen yogurt, sherbet, bulk and novelty frozen desserts (e.g., bars, sandwiches, cones) is a half cup with the equivalent metric quantity in parentheses. While we acknowledge that pelletized ice cream is a unique and totally new ice cream product, we believe that the half cup serving size is appropriate for this product. Therefore, the serving size for pelletized ice cream is a half cup with the equivalent weight in grams.

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

Sincerely yours,



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