

Appendix A

Pelletized Ice Cream

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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



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,



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



OCT 22 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 May 29, 2009, letter to the Food and Drug Administration (FDA) in which you thanked FDA for explaining the agency's position regarding the appropriate measurement and declaration of the net quantity of contents for pelletized ice cream. You requested that pelletized ice cream and frozen dessert manufacturers have until the next uniform compliance date of January 2, 2012 to revise their labels to a net weight declaration.

You stated in your letter that it has long been the practice of the ice cream and frozen dessert industry to declare the net quantity of contents of its products in terms of volume, not weight. You also stated that as affected member companies begin to comply with the new policy requiring declarations in terms of net weight, they will need to conduct new testing to ensure accurate declarations, and they will need to print and run labels. You further stated that many of these members have substantial existing stocks of labels, and given the seasonal nature of the affected products, it will take significant time to use this stock.

As you know, in the response letter dated April 17, 2009 to the International Ice Cream Association, FDA's decision to require a net weight declaration applied to pelletized ice cream products only and not to any other frozen dessert. Pelletized ice cream is a unique and new ice cream product that has emerged in the marketplace and our evaluation was limited to this type of product. We were not asked to evaluate other frozen dessert products, nor provided any information on any additional products that are in the marketplace. Further, we were not aware that there were similar questions regarding other frozen dessert products. It is FDA's understanding that there is a limited number of manufacturers of pelletized ice cream products and at least one manufacturer in the United States has been selling the product by net weight for more than a year. Thus, FDA believes that the one year compliance date from April 17, 2009 is an appropriate

Page 2 – Ms. Cary Frye

amount of time for manufacturers to change their labels from a volume declaration to a net weight declaration on pelletized ice cream products. Therefore, FDA is denying your request for manufacturers of pelletized ice cream and frozen desserts to have until the next uniform compliance date of January 2, 2012 to revise their labels.

However, the agency recognizes that individual manufacturers may need additional time to change their labels and may request additional time. Therefore, the agency believes that it would be appropriate to consider, on a case-by-case basis, whether to exercise enforcement discretion with respect to the April 17, 2010 date. Factors that the agency intends to consider in any request from a manufacturer for the agency to exercise enforcement discretion include; the explanation of why the request is being made, the number of existing labels that the manufacturer is requesting to use, the dollar amount associated with the number of labels to be used, and the estimate of the amount of time needed to exhaust existing labels the manufacturer is requesting to use. Manufacturers may submit their requests in writing to Felicia Billingslea, HFS-820, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutrition, Labeling, and Dietary Supplements, 5100 Paint Branch Parkway, College Park, Maryland 20740.

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

Sincerely yours,



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



May 14, 2010

Ms. Loretta A. Carey
Consumer Safety Officer
Food Labeling and Standards Staff
Office of Nutrition, Labeling, and Dietary Supplements
CF SAN, FDA
5100 Paint Branch Parkway
College Park, MD 20740
Sent Via E-mail to: Loretta.Carey@fda.hhs.gov

RE: IICA Additional Information on Pelletized Frozen Desserts Measurement and Net Contents Declaration.

Dear Ms. Carey:

The International Ice Cream Association (IICA) is providing this information in response to your request for additional information about pelletized frozen desserts before responding to our request for confirmation of the appropriate manner of declaring net content on these products.

Pelletized frozen desserts are unique and novel products that entered the market in 1988 with the pelletized frozen ice cream sold under the brand name Dippin' Dots™, which was predominantly sold in food service venues to consumers for immediate consumption. Due to the commercialization and development of processing technology, packaged pelletized ice cream entered the retail marketplace about four years ago. While Dippin' Dots and similar pelletized ice creams meet the standard of identity for ice cream specified in 21 C.F.R 135.110, some other pelletized frozen desserts do not meet the ice cream standard. These include the three flavors of Unilever's Popsicle Shots Ice Beads and four flavors of Kemps Itti Bitz Icee Bits currently on the market. We have provided two examples to demonstrate the different types of pelletized ice cream and frozen dessert products that are currently in the market place.

Regardless of whether the pelletized products meet the ice cream standard, they are manufactured and sold in much the same manner. In short, these products are beads of ice cream, water ice, sherbet or other frozen dessert that are quick frozen with liquid nitrogen. The beads are relatively small, but they can vary in shape and size.

In a June 27, 2008 meeting with officials from FDA's Office of Food Labeling, along with staff from the National Institute of Standards and Technology (NIST) Weights and Measures Division, IICA discussed the appropriate manner of net contents declarations for these pelletized products. In a follow-up letter to FDA in July 2008, IICA further explained its position that the net quantity of content statement for both pelletized ice creams and other frozen desserts should be a volumetric declaration that excludes the external air. At that time, IICA explained that such a declaration would be consistent with the volumetric declarations used on other ice cream and frozen dessert products. In response to a request to provide additional information, specifically with regard to the measurements used for other frozen novelties and the pros and cons associated with volumetric measures that include and exclude the external air, IICA provided this information in a September 8, 2008 letter.

On April 17, 2009, FDA sent a letter to IICA expressing its disagreement with the position that a volumetric declaration is appropriate. IICA and its members respected this decision and made the changes necessary to comply with the agency's position. Because FDA made clear in a subsequent October 22, 2009 letter that its decision "applied to pelletized ice cream only and not to other frozen dessert" and further noted "we were not aware that there were similar questions regarding other frozen dessert products," IICA sent its letter earlier this year seeking the agency's confirmation that indeed all pelletized frozen desserts should bear net content declarations in terms of weight, not volume.

As explained in that April 2, 2010 letter, the rationale that supported FDA's decision with regard to pelletized ice creams should apply to other pelletized frozen desserts. We see no reason for a departure. As a preliminary matter, 21 CFR 101.105(a) specifies that the quantity of contents be declared in terms of weight if the product is solid, semisolid, viscous, or a mixture of solid and liquid, unless there is a firmly established history of declaring the content of the product in terms of volume. Because pelletized ice cream is a unique and new product, FDA determined that this exception did not apply. We see no reason why a contrary rationale would be applied to pelletized frozen desserts, which are newer to the market than the pelletized ice creams. Additionally, we have provided updated information in the table below on the pros and cons of labeling pelletized frozen dessert with net weight declaration compared to the volume declaration used by conventional ice cream and frozen dessert products.

Further, as set forth in FDA's April 2009 letter, "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." Now that it has been determined that pelletized ice cream products must have net content statements in terms of weight, it would best facilitate value comparisons if all pelletized frozen desserts declared net contents in terms of weight. To determine otherwise would seem to run contrary to the dictates of the FPLA.

Because the National Conference on Weights and Measures will meet in early July and consider amendments to NIST Handbooks 130 and 133, including an amendment to reflect FDA's position with regard to net content statements for pelletized ice cream and frozen desserts, we would like the agency's timely confirmation of its position with regard to pelletized frozen desserts.

If you have any questions or require any further information, please feel free to contact me at (202) 220-3543 or via e-mail [at cfrye@idfa.org](mailto:cfrye@idfa.org).

Sincerely,

A handwritten signature in black ink that reads "Cary Frye". The signature is written in a cursive, flowing style.

Cary Frye
Vice President,
Regulatory Affairs

cc: G. June, ONDLS, FDA
K. Butcher, NIST
L. Warfield, NIST

Comparison of Volumetric Declaration and Measurement vs. Gravimetric (weight) for Pelletized Frozen Desserts		
Option	Pros	Cons
Label by weight	<ul style="list-style-type: none"> • Consistent with pelletized ice cream (FDA decision April 2009) • Measurement method will be easy to implement in the field • No concerns around product settling or melting 	<ul style="list-style-type: none"> • Method inconsistent with all traditional ice cream and novelties
Label by volume (Excluding external air)	<ul style="list-style-type: none"> • Method consistent with all other ice cream and novelties 	<ul style="list-style-type: none"> • Accurate measurement method needs to be developed • Water displacement methods are difficult to implement in the field • Inconsistency between Net Content declaration and Nutrition Facts Panel



Strawberry, Chocolate and
 Vanilla Flavored Ice Cream Beads



Itti Bitz Pelletized Ice Cream



Lemon Lime Flavored Ice Beads



Icee Bits Pelletized Frozen Dessert



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
 College Park, MD 20740

Martin Hahn
 Hogan & Hartson LLP
 Columbia Square
 555 Thirteenth Street, NW
 Washington, DC 20004

This is in response to your September 4, 2009 letter and subsequent e-mail dated February 2, 2010, on behalf of your client, Kemps, LLC. You are requesting an additional year exemption (through April 17, 2011) to exhaust current packaging inventory for your client's pelletized ice cream. As we understand these products are marketed under the IttiBitz brand, StoneRidge brand, Albertson's brand, and Jewel brand.

You advise that the labels for Kemps pelletized ice cream are being changed to reflect the Food and Drug Administration position that quantity of contents for pelletized ice cream should be expressed in units of net weight rather than fluid volume. As we understand, Kemps, LLC, has an overabundance of product labels because of the newness of the product lines, lower sales than projected, and the seasonal nature of the product. While we were not provided with existing and new labels for the products in question, you did provide us the following information regarding label inventory.

Brand	Flavor	label inventory as of 4/2010	Run out dates
IttiBitz	Neopolitan	551,019	12/2010
"	Mint Chip	149,152	6/2010
"	Strawberry Cheesecake	311,840	4/2011
"	Champions Chocolate	216,000	4/2011
"	Double Chocolate Stars	1,115,148	12/2010
"	Waffle Cone Twist	1,075,354	10/2010
StoneRidge	Cookies N Cream	109,274	4/2011
"	Banana Split	254,960	"
"	Neapolitan	232,981	"
"	Mint Chip	159,615	"
"	Cotton Candy	205,230	"
Albertson's	Cookies N Cream	156,412	4/2011
"	Banana Split	92,286	"
"	Neapolitan	168,412	"
"	Mint Chip	138,164	"
"	Cotton Candy	116,536	"
Jewel	Cookies N Cream	69,746	4/2011

2—Kemps

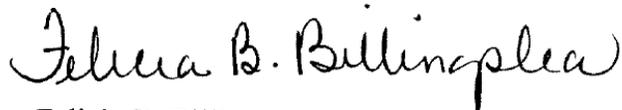
“	Banana Split	237,197	4/2011
“	Neapolitan	235,373	4/2011
“	Mint Chip	157,373	4/2011
“	Cotton Candy	167,197	4/2011

Based on the limited information you provided, FDA will agree to not take enforcement action against the products listed in the above table for reasons of incorrect declaration of the quantity of contents in terms of volume rather than net weight through the following dates:

- IttiBitz brand pelletized mint chip through June 30, 2010
- IttiBitz brand pelletized waffle cone twist through October 31, 2010
- IttiBitz brand pelletized neapolitan through December 31, 2010
- IttiBitz brand pelletized double chocolate stars through December 31, 2010.
- The remaining pelletized products in the above table through April 17, 2011

However, we expect that new labels with the proper quantity of contents declaration will be used on these products after the dates specified above.

Sincerely yours,



Felicia B. Billingslea
Director
Food Labeling and Standards Staff
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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