

Appendix E

Food and Drug Administration (FDA) Letter to the International Ice Cream Association (IICA)

on Uniform Compliance Date for Pelletized Ice Cream

(Letter dated October 22, 2009)

THIS PAGE INTENTIONALLY LEFT BLANK



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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

L&R Committee 2010 Interim Agenda
Appendix E – FDA Letter on Uniform Compliance Date for Pelletized Ice Cream

cc:

Kenneth S. Butcher
NIST Weights and Measures Division
Laws and Metric Group
100 Bureau Drive, M/S 2600
Gaithersburg, Maryland 20899-2600

Lisa Warfield
NIST Weights and Measures Division
Laws and Metric Group
100 Bureau Drive, M/S 2600
Gaithersburg, Maryland 20899-2600

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

Allan A. Zackler
Zackler & Associates
Attorneys at Law
3824 Grand Avenue, Suite 100
Oakland, California 94610

THIS PAGE INTENTIONALLY LEFT BLANK