



June 3, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: DOCKET NO. 2001N-0548:
Food Labeling; Guidelines for Voluntary Nutrition Labeling of Raw Fruits,
Vegetables, and Fish; Identification of the 20 Most Frequently Consumed Raw
Fruits, Vegetables, and Fish.
70 FR 16995 (April 14, 2005).**

We appreciate the opportunity to provide comments on the proposed Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish.

The U.S. Apple Association (USApple) is the only national trade association representing all sectors of the domestic U.S. apple industry, including growers, packers, shippers, marketers and processors. The association was originally organized in 1895.

The membership of USApple includes 36 state and regional apple associations representing the 7,500 apple growers throughout the United States, as well almost 300 individual firms involved in the apple business — growers, packers, shippers, processors and industry suppliers. USApple's mission is to provide the means for all segments of the U.S. apple industry to join in collective efforts to profitably produce and market apples and apple products. A priority of our education program is to provide consumers with accurate nutrition information in order to promote a healthy lifestyle.

USApple is member-driven, and works to unify a diverse industry to achieve three primary goals:

- Represent the entire industry on national issues;
- Grow demand for apples and apple products; and
- Provide vital information impacting the production and marketing of U.S. apples.

U.S. Apple commissioned Food Research, Inc. to assist us in reviewing and evaluating the agency's proposed changes in the apple nutrition label in 70 FR 16995. Food Research, Inc. is a scientific research firm with extensive experience in food and nutrition labeling regulatory issues, data management and database development, nutrient composition research, food consumption research, and other related topics.

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In its regulatory proposal, the Food and Drug Administration (FDA) is seeking to change the nutrition labeling values for four nutrients in apples: potassium, carbohydrate, dietary fiber, and iron. The proposed changes are based on nutrient data submitted by the U.S. Department of Agriculture (USDA) from its 2001-2002 sampling of fruits and vegetables.^{1,2} USDA submitted data on 5 varieties of apples: Red Delicious, Golden Delicious, Granny Smith, Gala, and Fuji. The submission included 12 to 26 data points for each nutrient, except that no data were submitted for vitamin C.

We have reviewed the data and accompanying information submitted by USDA, but we were unable to fully critique the values as there was not enough documentation accompanying the data.

21 CFR 101.45 (Guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish) states that FDA encourages the submission of nutrient data for the most frequently consumed raw fruits, vegetables, and fish. It also states, however, that the submission should include information about the source of the data (names of investigators, name of organization, place of analyses, dates of analyses), number of samples, sampling design, analytical methods, and statistical treatment of the data.³

In reviewing the USDA data submission, we were unable to determine for each data point: the place and date of sample collection, how samples were prepared for analysis (e.g., refuse removal, number and sources of samples in the composite, homogenization of sample material, preparation of aliquots), place and date of analysis, and the analytical method used. While some information was included about proximate analyses, one cannot determine which data point was analyzed by which laboratory and by which method. In addition, it is not clear whether the nutrient values are based on peeled or unpeeled apples.

Although the comment period on these proposed regulations is closing on June 3, 2005, we respectfully request that FDA continue to accept nutrient data for an additional 12 months, and then allow sufficient time for subsequent rigorous analysis, before publishing a final rule. This will allow time for sample collection and analysis of a range of fresh apple varieties during the extended apple harvest and marketing period.

Thank you for the opportunity to comment on these important proposed Guidelines. Please do not hesitate to contact me or Wendy Davis, USApple's Director of Communications and Consumer Health, with any questions you may have. Wendy can be reached at 703-442-8850 or wdavis@usapple.org.

Sincerely yours,

Nancy Foster
President & CEO
U.S. Apple Association

¹ USDA nutrient data submitted to FDA August 1, 2002 in a comment to the March 20, 2002 proposed rule, available on the internet at: <http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/080602/01n-0548-c000006-vol1.pdf>.

² 70 FR 16995 at 17004, Reference 1. Brandt, MM, memo to the file: Nutrient Data from U.S. Department of Agriculture received after close of comment period, Center for Food Safety and applied Nutrition, FDA, February 2005, available on the internet at: <http://www.fda.gov/OHRMS/DOCKETS/98fr/01n-0548-bkg0002-03-Tab-01-vol4.pdf>.

³ 21 CFR 101.45(b)(1)(ii)