



PEAR BUREAU NORTHWEST

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May 4, 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; Reopening of the Comment Period 70 Fed. Reg. 16995 (Apr. 4, 2005)

The Pear Bureau Northwest (Pear Bureau) appreciates this opportunity to submit comments concerning nutrition labeling values for fresh pears. Established in 1931, the Pear Bureau Northwest is a non-profit marketing organization that promotes, advertises and develops markets for fresh pears grown in Oregon and Washington. Oregon and Washington comprise the nation's largest pear producing region, producing approximately 84% of all fresh pears grown in the United States, and more than 94% of all winter pears (non-Bartlett varieties such as Bosc and Anjou). The 1,600 growers and 73 packers and shippers represented by the Pear Bureau Northwest take pride in their ability to produce top-quality fresh *USA Pears* for the world market.

The Pear Bureau has commissioned a statistical analysis of new pear data provided to FDA by the U.S. Department of Agriculture. 1/ This analysis, which takes into account the relative market share for each variety tested, was conducted using procedures outlined in FDA guidance for developing nutrition labeling values. 2/ The results support FDA's proposed values for pears of 0 g of total fat, 0 calories from fat, 16 g of sugars, and 0% of the calcium daily value (DV)

1/ Letter from Joanne M. Holden, Nutrient Data Laboratory to FDA Dockets Management Branch (Aug. 1, 2002).

2/ FDA Guidance for Industry, *Nutrition Labeling Manual—A Guide for Developing and Using Databases* (Mar. 1998).

2001N-0548

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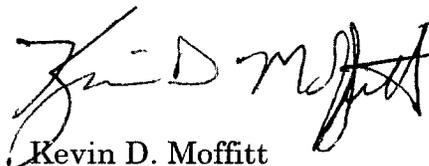
per serving, but indicate that the fiber value should be updated to 5 g and total carbohydrate to 26 g per serving. Copies of the summary report for the statistical analysis, a table of nutrition labeling values indicated, and pertinent market share data are attached.

The Pear Bureau respectfully requests that the nutrition values for pears in Appendix C to 21 C.F.R. Part 101 be updated to reflect the attached analysis. In the interest of providing consumers with updated values as soon as possible, we further request that FDA exercise enforcement discretion and permit use of these values, once confirmed, while the final rule is pending. We note, in this regard, that FDA has previously not objected to the use of updated nutrition labeling values pending completion of a final rule in this area. 3/

* * *

Thank you for your consideration of these comments. If there are any questions concerning this information, please do not hesitate to contact me or our food law counsel, Ann Boeckman of Hogan & Hartson. Ann can be reached at 202-637-5770.

Sincerely,



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Nutrient Composition of Fresh Pears Sold in the United States

Summary Report to Pear Bureau Northwest

March 29, 2005

Nutrient Data

For this research, Food Research, Inc. used the USDA data that was submitted to FDA in August, 2002 (comment on Proposed Amendments to Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish and Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish, Docket No. 01N-0548).

Four varieties of pears were collected from four U.S. regions in a market-basket sampling, as part of USDA's National Food and Nutrient Analysis Program (NFNAP). We contacted USDA to obtain the sample collection dates, which were October 2000 and May 2001.

Sample Weighting

There are an equal number of data points for each of the four varieties tested: Bartlett, Bosc, Green Anjou and Red Anjou. Because these varieties do not have equal market shares, we weighted the data according to the market share of each variety.

Pear Bureau Northwest provided the 2004 market share information for fresh pears sold in the U.S., including domestically-grown and imported. The source of the market share data is the Winter Pear Control Committee, the Federal Marketing Order for fresh pears grown in Oregon and Washington.

The four pear varieties that were tested represent approximately 85% of all fresh market pears sold in the U.S. We weighted the data according to the market share (metric tons) of each variety as follows: Bartlett 189,278, Bosc 88,065, Green Anjou 143,944 and Red Anjou 12,278.

Nutrition Labeling

We converted the weighted nutrient data to the FDA serving size of 166 grams (1 medium pear) and applied FDA nutrition labeling statistics, calculating the 95% prediction interval (PI) for each nutrient and then selecting the mean or PI, as appropriate, for the nutrition labeling value.

Table 1 summarizes the results of the statistical analysis and nutrition labeling values that are indicated by the analysis. For each nutrient, the table shows: number of data points (n), weighted mean, weighted standard deviation (SD), weighted 95% prediction interval value (PI), minimum and maximum value, rounded nutrition label value, and the basis for the label value (e.g., mean and/or PI). Percent Daily Values (% DV) are also shown for each nutrient for which a Daily Value has been established.

All of the results for carotenes (beta carotene, alpha carotene and beta cryptoxanthin) indicate a nutrition labeling value of zero for vitamin A. No data were provided for sodium, potassium, or vitamin C.

Table 1

**Pears: Weighted Nutrition Labeling Statistics
USDA Nutrient Data for 4 Varieties
166-gram Serving**

Nutrient	Unit	n	Mean	Mean %DV	SD	95% PI	95% PI %DV	Low	Low %DV	High	High %DV	Rounded Label	Rounded Label %DV	Label Basis
Calories	kcal	24	96.23		4.14	86.23		88.42		109.80		100		Mean
Fat Calories	kcal	24	1.75		1.00	2.91		0.14		4.17		0		PI & Mean
Fat	g	24	0.21	0.32%	0.12	0.35	0.54%	0.02	0.03%	0.50	0.77%	0	0%	PI & Mean
Carb	g	24	25.64	8.55%	1.17	29.49	9.83%	23.66	7.89%	29.52	9.84%	26	9%	Mean
Fiber	g	24	5.80	23.18%	1.10	4.84	19.37%	4.19	16.75%	7.44	29.76%	5	20%	PI
Sugars	g	24	16.28		1.44	15.66		14.07		19.57		16		PI & Mean
Protein	g	24	0.65		0.15	0.48		0.39		0.98		< 1		PI & Mean
Calcium	mg	16	9.96	1.00%	6.84	0.00	0.00%	6.49	0.65%	21.41	2.14%		0%	PI & Mean
Iron	mg	16	0.22	1.20%	0.22	0.00	0.00%	0.13	0.70%	0.93	5.19%		0%	PI

USA Pear Production and imports (2-05)

	<u>Fresh USA Grown Pears Sold Domestically</u>	<u>Fresh Imported Pears Sold Domestically</u>	<u>Total Fresh Pears Sold Domestically</u>	<u>Percent of Total</u>
Anjou	131,000	12,944	143,944	28%
Bartletts	105,000	84,278	189,278	37%
Bosc	55,287	32,778	88,065	17%
Red Anjou	11,000	1,278	12,278	2%
Comice	4,950	0	4,950	1%
Seckel	960	0	960	0%
Other Reds	975	3,962	4,937	1%
Other Varieties	1,215	8,278	9,493	2%
Packham	0	56,222	56,222	11%
Total Fresh Pears	310,387	199,740	510,127	

**the data in this chart represents only the domestic US marketplace, the data below contains total market information for bartletts.*

USA Bartlett Pear Production

Currently Bartlett pears are the only variety used in processing in any major way

	<u>Yearly Average Tonnage</u>
Processed Bartlett	297,862
Fresh Bartlett	<u>126,698</u>
Total Bartlett	424,560
Percent of Bartlett tonnage Processed	70%

Data expressed in Metric tons (2200 lbs)

data source: Winter Pear Control Committee, Northwest Fresh Bartlett Marketing Committee,
Oregon Bartlett Pear Commission