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June 1, 2005

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

RE: Docket No. 2001N-0548

Dear Food and Drug Administration:

On behalf of the California Avocado Commission (CAC), which represents over 6,000 California avocado growers, please accept these comments to the Proposed Rule titled "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," published in the April 4, 2005, Federal Register.

CAC thanks the FDA for the opportunity to comment on this Proposed Rule, and wishes to comment on three items regarding the label value for California avocados:

Saturated Fat

The new FDA proposed value for saturated fat in avocados is 1g, increasing from 0.5 g. CAC believes that the saturated fat value from the 2002 Proposed Rule (0.5g/30g serving size) is the correct interpretation of the 1993-1997 data CAC submitted to FDA. At that time, FDA calculated the mean value for saturated fat at 0.634g and the 95% prediction limit at 0.7495g, which rounds to a label value of 0.5g. Using the same data points and based on rounding rules as outlined in 21 CFR 101.9(c), CAC believes the label value should again round to 0.5g rather than 1g saturated fat. Please see attached Table 6.

Additionally, the USDA Nutrient Database for Standard Reference, Release 17 (NDB No: 09038) cites 0.638g saturated fat per 30g serving of avocado. CAC believes that consistency between FDA food labels and USDA databases is imperative to avoid consumer confusion and deliver a unified nutrition message. Indeed, CAC has received numerous inquiries from the media, the scientific community, and consumers questioning the difference in values between the FDA nutrition label and the USDA Nutrient Database values. Whenever possible and practical, CAC believes that FDA should consider USDA nutrient database values in addition to the agency's own 95% prediction limit when determining label values.

Fiber

The new FDA proposed value for fiber in avocados is 1g, decreasing from 3g. Based on the six data points CAC submitted to FDA during the 2002 comment period, CAC continues to contend that sample 23 should be excluded from statistical analysis because of its distant proximity to the next lowest data point for dietary fiber. Once sample 23 is excluded from the analysis, the mean becomes 2.574g and the 95% prediction limit becomes 2.2132g. Please note that there are no data points for dietary fiber below 1g; a 30 g serving will contain more than twice that amount 83% of the time. The data clearly support a label value of 2.0g dietary fiber (8% DV) per 30g

2001N-0548

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serving. Please see attached Tables 2 and 6 as well as Figures 1 and 2 below. (The Commission has made handwritten notations on Table 6 showing corrected value for dietary fiber).



Figure 1. Scattergram showing fiber distribution for all samples.



Figure 2. Scattergram showing fiber distribution for all samples.

Additionally, the USDA Nutrient Database for Standard Reference, Release 17 (NDB No:09038) cites 2 g dietary fiber per 30 g serving of avocado. As stated earlier, CAC supports consistency between the FDA value and USDA nutrient databases, all in order to promote a more unified nutrition message among government agencies.

Potassium

The new FDA proposed value for potassium is 140 mg, decreasing from 160 mg. CAC believes that the potassium value from the 2002 Proposed Rule (160 mg/30 g servings size) is the correct interpretation of the 1993-1997 data CAC submitted to FDA. At that time, FDA calculated the mean value for potassium at 173.6 mg and the 95% prediction limit at 164.3512g, which rounds to a value of 160 mg.

Additionally, the USDA Nutrient Database for Standard Reference, Release 17 (NDB No:09038) cites 152 mg potassium per 30 g serving of avocado, lending support to the 160 mg value rather than a value of 140 mg.

Finally, CAC would like to reference the letter submitted by the Produce Marketing Association, requesting that FDA extend the comment period for 12 months to allow interested parties to conduct additional testing and submit the results to FDA for consideration. CAC strongly supports an extended comment period to plan, execute, and evaluate additional nutrient research so that the data is as complete and extensive as possible.

Thank you for your review and consideration of the nutrient data from the California Avocado Commission.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark Affleck'.

Mark Affleck
President/CEO

Table 2
1993-1997 California Avocado Commission (CAC) Data
for Avocados ^A
Serving Size: 30 grams (raw)

SAMPLE ^B	LAB DATE	WATER (g)	ASH (g)	CALORIES (kcal)	CALORIES			SODIUM ^C (mg)	POTASSIUM (mg)	TOTAL CARBO- HYDRATE (g)	DIETARY FIBER (g)	SUGARS (g)	PROTEIN (g)	VITAMIN A (IU)	VITAMIN C (mg)	CALCIUM (mg)	IRON (mg)
					FROM FAT (kcal)	TOTAL FAT (g)	SATURATED FAT (g)										
9	01/19/93	23.22	0.54	39.31	29.88	3.57	0.58	.	.	1.92	.	0.00	0.75	39.99	.	.	.
10	01/19/93	23.04	0.45	39.53	28.63	3.42	0.48	.	.	2.19	.	.	0.90	37.50	.	.	.
11	01/19/93	23.55	0.36	37.76	28.12	3.36	0.50	.	.	1.95	.	.	0.78	42.51	.	.	.
12	10/04/93	19.32	0.48	69.80	58.25	6.96	1.19	.	.	2.73	.	0.06	0.51	30.00	.	.	.
13	10/05/93	20.04	0.63	62.74	51.48	6.15	0.85	.	.	2.40	.	.	0.78	50.01	.	.	.
14	10/19/93	20.64	0.45	57.93	45.70	5.46	0.77	.	.	2.64	.	.	0.81	35.01	.	.	.
15	04/28/94	21.18	0.42	55.13	43.94	5.25	0.70	2.45	185.40	2.49	.	.	0.66	.	3.18	4.50	0.159
16	05/02/94	20.85	0.81	56.88	47.46	5.67	0.79	3.93	192.00	1.89	.	.	0.78	.	2.46	3.30	0.158
17	05/06/94	23.88	0.66	33.38	24.36	2.91	0.38	5.10	207.30	1.89	.	.	0.66	.	2.88	2.26	0.196
18	12/29/94	23.34	0.30	35.49	22.35	2.67	0.44	.	145.80	3.09	.	.	0.60	.	3.90	5.70	0.174
19	01/03/95	22.50	0.42	42.22	29.63	3.54	0.58	9.81	182.10	2.88	.	.	0.66	.	2.70	2.96	0.183
20	01/04/95	21.60	0.57	50.50	39.42	4.71	0.79	4.02	195.60	2.46	.	.	0.66	.	4.17	4.41	0.227
21	05/09/96	20.04	0.54	59.48	45.20	5.40	0.73	3.12	184.20	3.21	2.73	.	0.81	.	2.16	3.36	0.233
22	05/13/96	20.79	0.60	51.27	35.91	4.29	0.53	2.47	163.20	3.54	2.25	.	0.78	.	2.16	2.84	0.206
23	05/15/96	20.28	0.84	55.26	41.18	4.92	0.65	3.21	187.20	3.24	1.29	.	0.72	.	2.76	3.09	0.149
24	02/17/97	19.89	0.60	60.97	47.21	5.64	0.86	3.24	148.20	3.15	2.82	.	0.72	.	2.31	4.17	0.255
25	02/19/97	22.05	0.39	18.99	38.42	4.59	0.62	1.74	152.40	2.46	2.16	.	0.51	.	2.61	4.80	0.169
26	02/24/97	22.26	0.57	42.30	29.13	3.48	0.53	1.57	139.80	3.21	2.91	.	0.48	.	2.55	5.04	0.089

^A These 18 samples have been sent to the FDA in various submissions as the samples have been collected by the CAC since 1993. The submissions since 1993 have also included the four samples from the PMA submissions and the four samples from the 1991 CAC submission. But, the sampling design and composite size for the 18 samples collected since 1993 differs from the 1989-1990 PMA and 1990 CAC sampling design and composite sizes. Since these 18 samples have a different composite size and sampling methodology than the earlier PMA and CAC samples, statistical analyses were done by using these data independently of the 1989-1990 PMA data and 1990 CAC data.

^B This sample number corresponds to the lot code found in the most recent CAC submission, an August 20, 1998 letter providing all samples (PMA and CAC) for avocados taken from 1989 to 1997.

^C No sodium values were given for samples 9-17 in the CAC 1996 submission, Proposal to Develop a Database for Nutrition Labeling California Avocados. But, in an August 20, 1998 letter from CAC providing nutritional measurements for newer samples since their last submission in 1996, a sodium value of 0.0 milligrams was given for sample 18, and nonzero values were given for samples 15-17 and 19-26. Since it was uncertain of whether sodium was not measured or the measured sodium level was 0.0 for sample 18, Karen Duester from The Food Consulting Company was contacted on behalf of the CAC on March 24, 1999. In this telephone conversation, Ms. Duester indicated that the lab sheet for sample 18 could not be located. As Ms. Duester reviewed previous versions of the avocado data for various dates throughout the study, the sodium value for sample 18 was blank for some versions and was 0.0 milligrams for other versions. With this uncertainty, the sodium value for sample 18 was assumed not to be measured and was assumed missing in the statistical analyses.

Table 6
Means, One-sided 95% Prediction Limits,
and Resulting Label Values for Avocados derived from
1993-1997 California Avocado Commission (CAC) Data
Using a Composite Size of 12 Units ^A
Serving Size: 30 grams (raw)

Nutrient (units)	Mean	Mean (%DV)	95% Prediction Limit	95% Prediction Limit (%DV)	Rounded Label Value	Label Value (%DV)	Choice ^B
ash (g)	0.535
water (g)	21.582
calories (kcal)					50.0		calc
calories from fat (kcal)	4.4135	6.790	5.3098	8.169	45.0		calc
total fat (g)	4.555	7.008	5.6065	8.625	58.0	49.0	pi
saturated fat (g)	0.634	3.169	0.7495	3.748	0.5	3.0	pi
cholesterol (mg)
sodium (mg)	3.085	0.129	4.3077	0.179	0.0	0.0	pi
potassium (mg)	173.600	4.960	164.3512	4.696	160.0	5.0	pi
total carbohydrate (g)	2.574	10.296	2.2132	4.853	2.0	1.0	calc
dietary fiber (g)	2.360	9.440	1.2960	5.184	21.0	44.0	pi
sugars (g)	0.030	.	0.2984	.	0.0	.	pi
protein (g)	0.698	.	0.6130	.	1.0	.	pi
vitamin A (IU)	39.170	0.783	30.370	0.607	.	0.0	pi
vitamin C (mg)	2.820	4.700	2.028	3.379	.	4.0	pi
calcium (mg)	3.869	0.387	2.393	0.239	.	0.0	pi
iron (mg)	0.183	1.017	0.125	0.695	.	0.0	pi

^A These label values were derived from 1993-1997 California Avocado Commission (CAC) data under the assumption of simple random sampling and with statistical methodology in the FDA Nutrition Labeling Manual unless otherwise specified. Since the actual composite size was 12 units, 12-unit composite samples were assumed when calculating the one-sided 95% prediction interval.

^B Below is an explanation of the feasible choices for selecting a value for the nutrition label.

"mean" - the mean was statistically selected and rounded for the label.

"pi" - the one-sided 95% prediction interval was statistically selected and rounded for the label.

"calc" - the label value was manually calculated with proximate formulae and label values statistically derived for other nutrients.