June 2, 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).

Dear Sir or Madam:

The California Strawberry Commission (CSC) is pleased to submit these comments on Docket No. 2001N-0548.

The California Strawberry Commission is a state government agency that represents an industry of approximately 510 growers and 75 shippers and processors. California is the nation's leading producer of strawberries, harvesting approximately 1.8 billion pounds of strawberries annually and representing 88% of the country's total fresh and frozen strawberry production.

The California Strawberry Commission has commissioned Food Research, Inc. to review and evaluate data submitted by USDA in its comment to the March 20, 2002 proposed rule and the resulting proposed nutrition labeling values for strawberries. In addition, Food Research, Inc. conducted research to determine the sugars, calcium, and iron content of fresh strawberries.

Food Research, Inc. is a scientific research firm specializing in food and nutrition labeling regulatory issues, data management and database development, nutrient composition research, food consumption research, and other related topics.

The purpose of these comments is to provide FDA with representative analytical data on the sugars, calcium, and iron content of fresh strawberries sold in the United States.

We urge FDA to carefully consider these comments and data, which clearly indicate the following labeling values for fresh strawberries: Sugars 8g, Calcium 2% DV, and Iron 2% DV per 147-gram serving.

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Sugars

In the USDA data, six of the eight sugar values range from 7 to 9 grams per serving. Two sugar values of zero appear to be data entry errors because in these data sets, USDA has reported calculated values, not zeros, for laboratory results that fall below the analytical detection limit.

The FDA proposed label value of 6 grams of sugar is based on the mean of eight values which include the two erroneous zeros. If the two zero values are removed, both the mean and the 95% prediction interval indicate a label value of 8 grams of sugar per 147 grams of strawberries.

This is confirmed by the Food Research study, in which all four analytical values round to 8 grams of sugar per serving. (See **Tables 1-2** in the attached report.)

Calcium

In the USDA data, six of the eight calcium values, as well as the mean, round to 2% DV per serving. Two values are unusually low, only 0.058% DV and 0.96% DV. The two low values are from the same composites that reportedly had 0 grams of sugar and also had the lowest iron values.

While there is uncertainty about those two sample composites, the USDA mean still rounds to 2% DV. It is only the 95% prediction interval value that indicates a 0% DV label value for calcium. We believe that the relatively large standard deviation caused by the two low results is skewing the prediction interval value below the mean.

In the Food Research data on strawberries, all four analytical calcium values round to 2% DV per serving, as shown in **Tables 3-4** of the attached report.

Because the preponderance of the USDA data and all of the Food Research data round to 2% DV, we feel that it is appropriate to use the mean as the basis for labeling calcium in strawberries at 2% DV per serving.

Iron

In the USDA data, seven of the eight iron values and the mean round to 2% DV. The one low data point is 0.9% DV. This value is from one of the same composites that had low calcium and zero sugar values. The 95% prediction interval value is below 2% because of the relatively high standard deviation.

All four of the values in the Food Research data also round to 2% DV per serving. (See **Tables 5-6** of the attached report.)

Again, because the preponderance of the USDA data and all of the Food Research data round to 2% DV, we believe that the mean is the appropriate bases for labeling iron in strawberries at 2% DV.

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 researcher, Charlene Rainey of Food Research, Inc. Charlene can be reached at 949/197-6066.

Sincerely yours,

Christine B. Christian
Director, Product Research and Information
California Strawberry Commission

Sugars, Calcium, and Iron Content of Fresh Strawberries
Data Submission to the Food and Drug Administration
June 2, 2005

Food Research, Inc. was commissioned by the California Strawberry Commission to design and implement this research for the purpose of determining appropriate nutrition labeling values for sugars, calcium, and iron in fresh strawberries. Samples were analyzed at Covance Laboratories, Inc. in Madison, Wisconsin.

Samples for Analysis

Fresh strawberries were collected in May 2005 during California's peak growing season, which is between April and June when all districts are in full production.

Four brands of strawberries were purchased from three supermarkets in Madison, Wisconsin. Varieties were not stated on the container labels, but information from the California Strawberry Commission indicates that one brand was the Camarosa variety, one was a proprietary variety, and the other two brands were either Camarosa, Ventana, or Diamante berries.

Twelve 16-oz containers or six 32-oz containers of each brand were purchased and delivered to Covance Laboratories on the same day.

Laboratory Analyses

Upon arrival at the laboratory, samples were immediately prepared for analysis. Stems and caps were removed and the edible portions from each brand were composited and analyzed separately.

Individual sugars were analyzed by gas chromatography and calcium and iron were analyzed by inductively coupled plasma-emission spectrometry (ICP). Table 7 lists the raw data per 100 grams.

Nutrition Labeling Calculations

We converted the laboratory data to the FDA serving size of 147 grams (8 medium berries) and applied FDA nutrition labeling statistics, calculating the mean, standard deviation, and 95% prediction interval (PI) for each nutrient to determine the nutrition labeling value.

Tables 1-6 show the individual data points, results of the statistical analyses, the nutrition labeling value, and the basis for selecting the labeling value for each nutrient. These results indicate the following nutrition labeling values for fresh strawberries: Sugars 8g, Calcium 2% DV, and Iron 2% DV.

Sugars

Fresh Strawberries—147-gram Serving

Table 1: Individual Data Points

Sample	Date	Covance Lab No.	Data (g)	Label (g)
1	5/12/2005	50502900	7.938	8
2	5/12/2005	50502901	8.085	8
3	5/12/2005	50502902	7.644	8
4	5/12/2005	50502903	8.232	8

Table 2: Nutrition Labeling Statistics

n	4
Mean	7.97
Standard Deviation	0.25
95% Prediction Interval (PI)	7.20
Rounded Label	8
Label Basis	Mean

Calcium

Per 147g Fresh Strawberries

Table 3: Individual Data Points

Sample	Date	Covance Lab No.	Data (mg)	Data (%DV)	Label (%DV)
1	5/12/2005	50502900	13.392	1.34%	2%
2	5/12/2005	50502901	11.760	1.18%	2%
3	5/12/2005	50502902	17.934	1.79%	2%
4	5/12/2005	50502903	13.318	1.33%	2%

Table 4: Nutrition Labeling Statistics

n	4
Mean	14.10
Mean % DV	1.41%
Standard Deviation	2.66
95% Prediction Interval (PI)	8.87
95% PI % DV	0.89%
Rounded Label % DV	2%
Label Basis	Mean & Low

Iron

Per 147g Fresh Strawberries

Table 5: Individual Data Points

Sample	Date	Covance Lab No.	Data (mg)	Data (%DV)	Label (%DV)
1	5/12/2005	50502900	0.226	1.26%	2%
2	5/12/2005	50502901	0.245	1.36%	2%
3	5/12/2005	50502902	0.387	2.15%	2%
4	5/12/2005	50502903	0.360	2.00%	2%

Table 6: Nutrition Labeling Statistics

n	4
Mean	0.30
Mean % DV	1.69%
Standard Deviation	0.08
95% Prediction Interval (PI)	0.12
95% PI % DV	0.65%
Rounded Label % DV	2%
Label Basis	Mean & Low

Raw Data

Per 100g Fresh Strawberries

Table 7: Analytical Results

Sample	Date	Covance Lab No.	Fructose (g)	Glucose (g)	Sucrose (g)	Sugars* (g)	Calcium (mg)	Iron (mg)
1	5/12/2005	50502900	2.100	1.700	1.600	5.400	9.110	0.154
2	5/12/2005	50502901	2.300	1.800	1.400	5.500	8.000	0.167
3	5/12/2005	50502902	2.200	1.800	1.200	5.200	12.200	0.263
4	5/12/2005	50502903	2.200	1.800	1.600	5.600	9.060	0.245

* Results for galactose, lactose, and maltose were < 0.1 g per 100 g.

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