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Ann M. Boeckman
Hogan and Hartson
555 Thirteenth Street, NW
Washington, DC 20004-1109

Dear Ms. Boeckman:

This is in response to your letter of August 25, 2005, to the Food and Drug Administration (FDA), on behalf of your client, the Pear Bureau Northwest (Pear Bureau). In your letter, you requested confirmation that the FDA would not object to the use of updated nutrition labeling values for fresh pears while the agency completes its final rule on the nutrition labeling of fresh produce. You noted that the pear values presently used in FDA's fresh produce program have long been outdated, but that new and reliable nutrition labeling values for pears are now available based upon data provided by the U.S. Department of Agriculture (USDA) and analyzed using well-established FDA procedures for developing nutrition labeling information. You stated that you believe that the new pear values that the Pear Bureau submitted to FDA in response to the agency's April 2005 request for comments on the pending rulemaking will ultimately be acceptable to the agency when the final rule is completed.

You explained that the Pear Bureau submitted a statistical analysis of the new USDA pear data as well as market share data for the tested varieties, and requested that values for fiber be updated to 5 g and total carbohydrate to 26 g. You also noted that the new values included in the statistical analysis reflect changes in two key nutrients: dietary fiber is now 5 g (not 4 g), and fat is 0 g (not 1 g) [which is already consistent with the value for total fat in proposed appendix C to part 101]. You stated further that informing consumers of these values would better promote pear consumption, consistent with recommendations in the 2005 *Dietary Guidelines for Americans* and MyPyramid for increased fruit and vegetable consumption.

On April 4, 2005, FDA published in the Federal Register (70 FR 16995) a document to reopen the comment period for the proposed rule we published on March 20, 2002 (67 FR 12918) to update the guidelines and nutrition labeling values for the voluntary nutrition labeling of raw fruits, vegetables, and fish. We reopened the comment period to allow all interested parties the opportunity to review our tentative nutrition labeling values based upon data we received within and after the comment period, and to comment on the additional nutrient data. We also stated that we would evaluate any new data submissions during the reopened comment period and would consider use of those data in a final rule.

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FDA recognizes and commends the Pear Bureau for its submission of market share data for four varieties of pears in response to the 2005 reopening of the comment period. We used the market share data to derive the nutrition labeling values for the final rule for the voluntary nutrition labeling of raw fruits, vegetables, and fish, which we hope to publish in FY2006.

We stated in the 2005 reopening of the comment period, and as noted in the 2002 proposed rule, we believe that the values in proposed appendices C and D to part 101 could be used on an interim basis prior to completion of the rulemaking, provided that the nutrition information is presented in a manner consistent with the published documents. However, firms should be aware that values included in a final rule may differ and would need to be changed. Thus, the pear industry may now use the nutrition labeling values we published in the 2005 reopening of the comment period, which are based upon data USDA submitted within and after the comment period for the 2002 proposed rule. Those nutrition labeling values are listed in Table 1.

Table 1: Proposed Nutrition Labeling Values for Pears

Calories 100
Calories from fat 0
Total fat and saturated fat, 0 g, 0% DV
Trans fat 0 g
Cholesterol 0 mg, 0% DV
Sodium 0 mg, 0% DV
Potassium 180 mg, 5% DV
Total carbohydrate 25 g, 8% DV
Dietary fiber 4 g, 16% DV
Sugars 16 g
Protein 0 g
Vitamin A 0 % DV
Vitamin C 10% DV
Calcium 0 % DV
Iron 0 % DV

We acknowledge that there may be changes in final rule values for pears due to consideration of market share in their derivation, but we cannot at this time of rulemaking make public those final nutrition labeling values. Furthermore, we cannot authorize the use of nutrition labeling values for the voluntary nutrition labeling of raw fruits, vegetables, and fish that we have not provided or cross validated. Section 101.45(b) states that nutrition label values provided by the FDA in appendices C and D to part 101 for the 20 most frequently consumed raw fruits, vegetables, and fish listed in § 101.44 shall be used to ensure uniformity in declared values. We understand the Pear Bureau's sense of urgency to use new data and encourage them to promote the use of nutrition labeling at the point of purchase in retail stores and on packaging of fresh pears while anticipating the publication of the final rule.

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For additional information on the status of the final rule or on the voluntary nutrition labeling program of raw fruits, vegetables, and fish, please contact Dr. Mary Brandt at 301-436-1788 or at mary.brandt@fda.gov.

Sincerely,

A handwritten signature in black ink that reads "Barbara Schneeman". The signature is written in a cursive style with a long, sweeping tail on the final letter.

Barbara O. Schneeman, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition