

Docket No. 00Q-1582
Tab 8



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VIA FACSIMILE AND REGULAR MAIL

Dr. Lynne Larsen, Director
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Re: Tropicana Products, Inc.: Potassium Containing Foods Authoritative Statement Claim Notification

Dear Dr. Larsen:

On behalf of Tropicana Products, Inc. ("Tropicana"), I make the following supplements to the "Notification For A Health Claim Based On An Authoritative Statement For Potassium Containing Foods," submitted by Al Bolles on July 3, 2000. These amendments are made without prejudicing the 120-day notification period set forth in section 303 of the Food and Drug Administration Modernization Act of 1997 ("FADAMA").

1. Revised Table 5

Table 5 (page 22) of the notification has been revised to reflect potassium content of the example foods based on the reference amount customarily consumed (RACC). This is not meant to be a list of foods which may qualify for the proposed health claim, but to serve as illustrative examples. The requirement that foods which bear the proposed health claim meet the regulatory requirements set forth in 21 C.F.R 101.14 and also meet the requirements for low sodium set forth in 21 C.F.R. 101.61 is included as a footnote to the Tables. Table 5 (page 22) is attached.

2. Remove Table 6

Table 6, Appendix E (page 52) of the notification should be removed. The partial list of potassium containing foods is not an essential element of the notification.

Sincerely,

Nancy Green, Ph.D.
Vice President, Nutritional Products

Table 5. Partial list of foods containing more than 10% DV for Potassium per RACC.

Description	Amount	Potassium (mg)	*DV (%)
Apricots, dried, uncooked	40 g	740	21
Yam, ckd	110 g	737	21
Prune juice	240 mL	663	19
Tomato juice	240 mL	535	15
Clams, ckd	85 g	536	15
Banana	140 g	554	15
Orange juice, fresh	240 mL	480	14
Chard, swiss, raw	85 g	467	13
Kiwi	140 g	465	13
Banana chips	30 g	460	13
Cod, ckd	85g	439	12
Potato flesh, baked	110 g	430	12
Spinach, ckd	85 g	396	11
Grapefruit juice, fresh	240 mL	389	11
Orange-grapefruit juice	240 mL	379	11
Trout, ckd	85 g	380	11

As outlined in the notification, foods that bear the proposed health claim must meet regulatory requirements of 21 C.F.R. 101.14 and qualify as low sodium as outlined in 21 C.F.R. 101.61.

Attachment 1