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September 8, 2000

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**VIA FACSIMILE AND REGULAR MAIL**

Dr. Lynn Larsen, Director  
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-830)  
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. Authoritative Statement Citations**

Page 13 of the notification contains a citation from page 660 of the National Academy of Sciences consensus report entitled *Diet and Health: Implications for Reducing Chronic Disease Risk*. The citation should also include reference to page 11 of the *Diet and Health Report*, indicating that the authoritative statement is contained in both the Executive Summary and Conclusions sections of the document.

**2. Model Claim**

The model claim set forth on pages 4 and 10 of the notification is amended to read:

***Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke.***

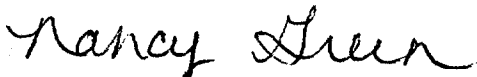
### **3. Revised Table 5 and Table 6, Appendix E**

Table 5 (page 22) and Table 6, Appendix E (page 52) of the notification are revised to reflect potassium content of 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) and Table 6, Appendix E (Page 52) are attached (Attachments 1 and 2).

### **4. Confidentiality**

Tropicana does not object to the Food and Drug Administration making public the July 3, 2000 notification and this letter, on October 31, 2000, the day the 120-day notification period set forth in FADAMA expires.

Sincerely,



Nancy Green, Ph.D.

Vice President, Nutritional Products

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

<b>Description</b>	<b>Amount</b>	<b>Potassium (mg)</b>	<b>*DV (%)</b>
Apricots, dried, uncooked	40 g	740	21
Yam, ckd	110 g	737	21
Prune juice	240 mL	663	19
Potato flesh, baked	148 g	578	17
Broccoli, ckd	148 g	540	15
Tomato juice	240 mL	535	15
Clams, ckd	84 g	530	15
Salt substitute	1 g	500	14
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	84 g	450	13
Winter squash	116 g	406	12
Banana	126 g	400	11
Onions, ckd	240 g	398	11
Spinach, ckd	85 g	396	11
Grapefruit juice, fresh	240 mL	389	11
Orange-grapefruit juice	240 mL	379	11
Trout, cooked	84 g	370	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

## Appendix E

**Table 6. Partial List of Potassium Containing Foods**  
(Source: USDA Standard Reference 13)

<b>Types</b>	<b>Description</b>	<b>Amount</b>	<b>Potassium (mg)</b>	<b>*DV (%)</b>
a	Apricots, dried, uncooked	40 g	740	21
b	Yam, ckd	110 g	737	21
a	Prune juice	240 mL	663	19
b	Potato flesh, baked	148 g	578	17
b	Broccoli, ckd	148 g	540	15
b	Tomato juice	240 mL	535	15
c	Clams, ckd	84 g	530	15
d	Salt substitute	1 g	500	14
a	Orange juice, fresh	240 mL	480	14
b	Chard, swiss, raw	85 g	467	13
a	Kiwi	140 g	465	13
a	Banana chips	30 g	460	13
c	Cod, ckd	84 g	450	13
b	Winter squash	116 g	406	12
a	Banana	126 g	400	11
b	Onions, ckd	240 g	398	11
b	Spinach, ckd	85 g	396	11
a	Grapefruit juice, fresh	240 mL	389	11
a	Orange-grapefruit juice	240 mL	379	11
c	Trout, cooked	84 g	370	11
d	Milk	240 mL	365	10
b	Tomato, red ripe	148 g	360	10
d	Yogurt	225 g	350	10
b	Celery, raw	110 g	350	10
b	Soy milk	240 mL	345	10
b	Black beans	90 g	320	9
b	Parsnips	85 g	319	9
a	Honeydew	134 g	310	9
a	Prunes	40 g	301	9
a	Raisins, seedless	40 g	300	9
b	Mushrooms	84 g	300	9
c	Lobster, ckd	84 g	300	9
a	Nectarines	140 g	300	9
b	Artichoke, ckd	84 g	297	8
c	Ocean perch, ckd	84 g	290	8
c	Flounder, ckd	84 g	290	8
c	Beef, flank, ckd	85 g	286	8
a	Cantaloupe	134 g	280	8

## Appendix E

**Table 6. Partial List of Potassium Containing Foods  
(Source: USDA Standard Reference 13) (cont.)**

b	Carrots, raw	78 g	280	8
c	Scallops, ckd	84 g	280	8
a	Dates	40 g	270	8
b	Cauliflower, raw	99 g	270	8
a	Strawberries	147 g	270	8
b	Brussel sprouts	85 g	269	8
b	Pumpkin, canned	130 g	268	8
c	Pork chop	85 g	258	7
b	Tomato puree	60 g	256	7
b	Corn, sweet, ckd	90 g	240	7
b	Sweet potato, boiled w/o skin	130 g	239	7
d	Peanut butter	2 TBSP	239	7
c	Catfish, ckd	84 g	230	7
b	Radish, raw	85 g	230	7
a	Watermelon	280 g	230	7
b	Asparagus, ckd	93 g	230	7
c	Turkey	85 g	229	7
b	Tomato sauce, canned	60 g	223	6
c	Crab meat, ckd	85 g	223	6
b	Collards, ckd	85 g	221	6
b	Eggplant, ckd	85 g	210	6
a	Pears, raw	166 g	210	6
b	Peas, green, raw	85 g	207	6
b	Kale, ckd	85 g	194	6
a	Peaches, raw	98 g	190	5
c	Chicken	85 g	180	5
b	Kidney beans	90 g	175	5
b	Avocado, raw	30 g	170	5
d	Nuts, dry roasted	30 g	169	5
d	Coffee, prepared w/tap water	240 mL	128	4

Types of foods

a. Fruits

b. Vegetables

c. Meats and sea foods

d. Others

\*Daily Value (DV) = 3500 mg

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.