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Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Attn: Docket Numbers ~~1994P-0390~~ and 1995P-0241

To whom it may concern:

POM Wonderful LLC, a subsidiary of Roll International Corporation, is the largest producer and marketer of the Wonderful® variety of pomegranates, and the producer of POM Wonderful® pomegranate juices – the only super-premium, refrigerated 100% pomegranate juice commercially available in the United States. We appreciate the opportunity to respond to FDA's request for comments on the 10 percent minimum nutrient contribution requirement for health claims.

POM Wonderful currently markets five pasteurized, bottled juice products consisting of 100% juice with no added sugar or preservatives. These products are composed solely of pomegranate juice from concentrate (or a blend of pomegranate and tangerine, cherry, blueberry, mango, pineapple, blackberry or orange juice) and natural flavors.

POM Wonderful strongly believes that processed fruit and vegetable products that are composed solely of fruits or vegetables be exempt from the 10 percent nutrient contribution requirement for health claims. FDA has already made this proposal for products without any additional ingredients (60 FR 66206, 66213, December, 21, 1995),

The agency agrees with the arguments raised in the petitions that certain fruits, vegetables, and grain products that otherwise meet the requirements of the specific health claim should be able to bear the claim even though they do not contain 10 percent of one of the six listed nutrients because these foods comprise a major part of a balanced and healthful diet, and because current dietary guidance promotes consumption of these foods.

However, FDA did not propose to extend this exemption to products composed solely of fruits or vegetables that also contain minor non-nutrient ingredients (e.g. flavors). POM Wonderful strongly recommends that such products be included in the exemption from the 10 percent nutrient contribution requirement for health claims if the ingredients they contain do not significantly affect nutrient content as defined in 21 CFR § 101.9(f)(1). The rationale for our recommendation is provided below:

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Fruits and vegetables (including 100% juices) are recommended components of a healthy diet

Fresh, frozen and canned (bottled) fruits and vegetables (including 100% juices) are foods that help consumers maintain healthy dietary practices. As FDA noted (see above) frequent consumption of fruits and vegetables is consistent with the Dietary Guidelines for Americans (60 FR 66206 at 66213). In addition, the Food Guide Pyramid (U.S Department of Agriculture, 1996) recommends 2-4 servings of fruit (including 100% fruit juice) per day as part of a healthy diet. The American Academy of Pediatrics (Committee on Nutrition, 2001) has concluded, "One hundred percent fruit juice or reconstituted juice can be a healthy part of the diet when consumed as part of a well-balanced diet." Finally, numerous public health initiatives including the National Cancer Institute's Five-A-Day program¹ have been designed to promote increased consumption of fruits and vegetables (including 100% fruit juices) in the United States.

The addition of minor ingredients to fruits and vegetables does not undermine their health benefits

The addition of minor ingredients (e.g. natural flavors) to 100% fruit juices does not diminish their beneficial contribution to the diet and may be important to ensure consumer acceptability. For example, POM Wonderful® pomegranate juice is a rich source of phenolic compounds including anthocyanins, tannins and other bioactive compounds that are believed to have important health benefits (Gil *et.al.*, 2000; Pérez-Vicente *et.al.* 2002). Clinical studies have shown that human subjects fed pomegranate juice experienced reduced platelet aggregation (Aviram *et.al.*, 2000), reduced susceptibility of serum low density lipoprotein cholesterol (LDL-C) to oxidation (Aviram *et.al.*, 2000, 2002, 2004), reduced carotid artery intima-media thickness (Aviram *et.al.*, 2004) and reduced serum angiotensin converting enzyme activity and systolic blood pressure (Aviram and Dornfeld, 2001).

FDA has already recognized that minor ingredients in fruits and vegetables do not detract from their health benefits. The agency used this reasoning to exempt canned and frozen single ingredient fruit and vegetable products from the 10 percent nutrient contribution requirement for use of the claim "healthy" (63 FR 14349, 14353, March 25, 1998),

...fruit and vegetable products that have nonnutritive added ingredients (such as water, spices, or flavors) maintain comparable nutrient profiles to the raw versions, and therefore, would be permitted to bear the claim under the same conditions as the raw versions. Accordingly, the agency is amending § 101.65(d)(2)(iv) from the proposal to clarify that foods comprised solely of fruits and vegetables may have added ingredients such as water, spices, flavors or other additives that do not change the level of nutrients in the food.

More recently, FDA used this approach to allow whole or chopped nut products with minor ingredients to bear the qualified health claim for nuts and reduced risk of coronary

¹ <http://www.5aday.gov/index-quick.shtml>

heart disease². Such products are eligible to bear the claim as long as the added ingredients do not significantly alter their nutrient content as defined by 21 CFR § 101.9 (f)(1).

POM Wonderful wholeheartedly agrees with this approach and strongly recommends that it be used to grant the proposed exemption for “100%” fruit and vegetable products that contain ingredients that do not significantly change their nutrient content. Canned or frozen fruit and vegetable products that contain ingredients that significantly change their nutrient content (e.g. sauces, syrups, added sugars) as set forth in 21 CFR § 101.9 (f)(1) would *not* be granted such an exemption.

The integrity of health claims would be maintained

The purpose of the 10 percent nutrient contribution requirement is to “...assure that the value of health claims would not be trivialized or compromised by their use on foods of little or no nutritional value.” (60 FR 66206 at 66211). However, the agency has concluded that such concerns do not apply to fruits and vegetables regardless of their micronutrient content

...diets high in fruits, vegetables, and grain products have been associated with various specific health benefits, including lower occurrence of coronary heart disease and of some cancers...and therefore, are exactly the types of foods that should be included in the diet to reduce the risk of specific diet-related diseases. Precluding such foods from bearing health claims could confuse consumers and undermine the utility of health claims. (Id. at 66213)

Summary and conclusions

In summary, POM Wonderful strongly recommends that “100%” fruit and vegetable products that contain minor ingredients that do not significantly alter their nutrient content should be exempted from the 10 percent nutrient contribution requirement for health claims. This recommendation is consistent with current governmental nutrition recommendations, reflects FDA’s existing and proposed labeling regulations and preserves the integrity of health claims.

POM Wonderful appreciates the opportunity to express our opinion, and looks forward to favorable consideration of this request.

Respectfully submitted,



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² <http://www.cfsan.fda.gov/~dms/qhcnuts2.html>

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