

April 7, 2002

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

8369 '02 APR 12 P1:19

PETITION TO ISSUE REGULATION

To Whom It May Concern:

INTRODUCTION

My name is Arthur Blank and my newly formed company will produce and market a new generation performance beverage in the sports drink market. The new product gives individuals the benefit of rapid rehydration and proper energy restoration before, during and after physical exertion. The aim in my submitting this petition is to apprise the FDA of an impending need for better product labeling of sports and energy beverages. Not only will this enhance the American consumers' ability to decide on a product that is most beneficial, but it will maintain a higher degree of honesty and integrity of product claims.

BACKGROUND

Within the beverage market category generally known as "sports drinks", there has been little or no FDA regulatory efforts addressing that specific category. Although the various ingredients of the myriad of available sports drinks are similar and accepted by the FDA, the actual performance value of these beverages vary considerably, ranging from mediocre to useless.

Any beverage (a solution) can be characterized by its ability to be digested and absorbed into the blood stream of humans. This feature is typically categorized into one of three levels of solute concentration: a) *hypotonic*, b) *isotonic*, or c) *hypertonic*. Each of these categories is further characterized by a numerical value of solutes called *osmolality*. Osmolality is expressed by the numerical value followed by the term, "mOsmol/l" (i.e. 210mOsmol/l). A beverage that is hypotonic does not require further digestion, therefore, is most desirable in terms of rapid fluid replacement. Both isotonic and hypertonic beverages require extended residence in the stomach for digestion. "There is good evidence that hypotonic solutions are more effective when rapid rehydration is desired".¹ Since the body uses its fluids for digestion, its dehydrating condition is further exacerbated before any new fluids are finally absorbed. This characteristic can be harmful in some situations of accelerated dehydration. Optimally, isotonic and hypertonic beverages are not conducive to rapid rehydration.

The performance of a sports drink primarily relates to fluid replacement in humans. Secondly, these drinks may or may not address energy restoration. However, in the United States, the abundant marketing campaigns generated by the dominant producers of sports drinks or thirst quenchers marketed through sports have over-shadowed the lagging technology needed to properly address fluid and energy restoration in humans. While the technology in the United States has been somewhat stagnant, the development of better performing beverages have been on the rise in other countries.

¹ Wapnir RA & Lifshitz F; 1985; Osmolality and Solute Concentration – Their Relationship with Oral Rehydration Solution Effectiveness; Pediatric Research, 19, 894-898.

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Following recent mass media exposure of the adverse effects (including death) of dehydration in athletes, there has been a heightened public concern for proper hydration and related products that perform effectively. This very issue of public attention is the target of marketing and advertising claims made by the producers of sports drinks, regardless of product performance. This elevated consumer concern has set the stage for a deluge of products to be introduced into the U.S. market.

PROBLEM

Being the target of massive marketing ploys, the general public has come to assume the fallacy that beverages "perceived" to be sports drinks will be healthful to them in dealing with the effects of dehydration.

With the increased consumer demand for products that can truly perform in terms of proper hydration, certain claims will be made by producers as to their products' performance capabilities. These claims, whether true or false, currently do not have to be substantiated to the consumer. Without the requirement for substantiating claims, the consumer will become the victim of misleading and confusing advertising campaigns that carelessly offer operative terminology such as "hypotonic" or "isotonic". This could, in turn, be detrimental to the consumer.

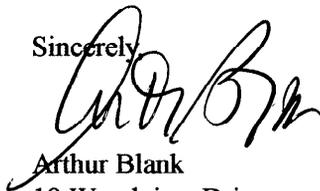
RECOMMENDATION

Enhance the labeling requirements for sports drinks (including products perceived to be sports drinks) and energy drinks to incorporate a statement of osmolality and tonicity. A suggested format would be to show the osmolality value within the label area of "NUTRITION FACTS" (such an example would be: **Osmolality:** 210mOs/l). Elsewhere on the label, perhaps following the ingredient list, should be a statement such as, "This product is **hypotonic**". Since all beverages have a tonicity characteristic and an osmolality value, the information is readily available to all beverage producers.

With this information being stated on product labels, the American consumers will have a better understanding of that product's capabilities of performing and will have a better chance of using a beneficial product. This type of required information will also help to create a natural market oversight of product claims.

I am hopeful that the FDA will recognize the need for this type of regulation within the sports and energy drink sector of the beverage industry and that this petition will be granted. If there are any questions regarding this petition, please do not hesitate to contact the undersigned.

Sincerely,



Arthur Blank
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Doylestown, PA 18901

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April 15, 2002

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PETITION TO ISSUE REGULATION (ADDENDUM)

ATTENTION: Helen K. Harris

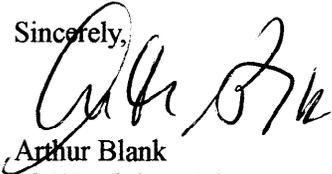
ENVIRONMENTAL IMPACT

Pursuant to Title 21; Parts 25.30 – 25.34, this action is categorically excluded from requiring a statement of environmental impact.

CERTIFICATION

I, Arthur Blank, hereby acknowledge that, to the best of my knowledge and belief, the previously submitted Petition to Issue Regulation includes all information and views relevant to the petition, favorable or not.

Sincerely,



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Arthur Blank
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