September 26, 2007

Barbara Schneeman, Ph.D.
Director, Office of Nutritional Products, Labeling, and Dietary Supplements
5100 Paint Branch Parkway
College Park MD 20740-3835

Dear Dr. Schneeman:

The Center for Science in the Public Interest requests that the Food and Drug Administration halt the use of unapproved health claims on beverages manufactured by Fuze Beverage LLC of Englewood Cliffs, New Jersey, which is owned by the Coca-Cola Company.¹ Such claims cause the products to be misbranded under Section 403(r)(3)(B), 21 U.S.C. § 343(r)(3)(B).

These unapproved health claims appear on Fuze Beverage labels and on the company website www.drinkfuze.com, to which the label directs consumers “for more info” or to “visit us.” FDA has concluded that a reference on the product label to additional material on a company’s Website causes the material to be “labeling” subject to FDA’s jurisdiction.²

Under the NLEA, a food or dietary supplement may not claim to cure, prevent, or treat a disease unless the claim is approved by the FDA as a “health” claim following a rulemaking proceeding or a decision by FDA not to challenge a notification of a claim based upon an authoritative statement from another government agency with scientific expertise.³

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³ FDCA §§ 403(r)(2)(B) and (C), 21 U.S.C. §§ 343(r)(2)(B) and (C)
The following health claims by Fuze Beverage LLC do not appear on FDA's list of approved health claims.4

1. The labels on Fuze Vitalize blackberry grape and orange mango fruit-flavored beverages (see Attachments 1 and 2) and the www.drinkfuze.com website5 to which consumers are directed by the labels, under Products, Refresh, vitamin A (see Attachment 3) make this unapproved health claim (see Attachments 1, 2, and 3):

   “Helps reinforce resistance to colds, influenza & infections of the kidneys, bladder and lungs.”

2. The label for Fuze Oolong Tea (See Attachment 4) and the www.drinkfuze.com website6, under Products, Teas, Polyphenols (see Attachment 5) make this unapproved health claim:

   “Regular consumption of Polyphenols are associated with reduced risk of developing cardiovascular disease and certain cancers.”

3. The website www.drinkfuze.com7, under Products, Refresh, Vitamin B-3 (see attachment 6), makes this unapproved health claim for the four Fuze Refresh beverages (see Attachment 6):

   “Known to improve circulation and reduce the cholesterol level in the blood.”

We ask that those and any other Fuze products that make unapproved health claims be taken off the market until they comply with FDA regulations.

Respectfully submitted,

David Schardt
Senior Nutritionist

Stephen Gardner
Director of Litigation

cc: Robert E. Brackett, Ph.D.
Director, Center for Food Safety and Applied Nutrition

Joseph R Baca
Director, Office of Compliance
Center for Food Safety and Applied Nutrition
Attachment 1
AMOUNT PER BOTTLE

Vitamin A - 11,250 IU
An antioxidant essential for vision, growth, healthy skin and reproduction. Helps reinforce resistance to colds, influenza & infections of the kidneys, bladder and lungs.

Vitamin C - 202 mg
An antioxidant essential for vision, growth and healthy skin. Known to promote healing.

Vitamin E - 67 IU
A strong antioxidant that aids in neurological and reproductive development. Promotes healthy nerve and brain function, reducing inflammation and known to slow the aging process.

Electrolytes - 441 mg
Magnesium, Calcium, and Potassium are electrolytes that control how and where fluids are distributed. They help muscles contract and relax, regulate nerve impulses to help our body respond to it's full potential.

drink:Fuse.com
Fuze Facts:
Each bottle of Fuze Refresh has 100% of your Recommended Daily Allowance of essential vitamins and bone building calcium.
Polyphenols - 12mcg
Powerful antioxidants that can protect cell membranes and cells DNA from the damaging effects of free radical induced oxidative damage.
Regular consumption of Polyphenols is associated with reduced risk of developing cardiovascular disease and certain cancers.

Folic Acid* - 225mcg
A water soluble B-Vitamin that helps build and maintain healthy cells.

Vitamin C - 135mg
An antioxidant essential for vision, growth & healthy skin. Known to promote healing.

Vitamin E - 17 IU
A strong antioxidant that aids in neurological and reproductive development. Promotes healthy skin and hair. Reduces scarring & is known to slow the aging process.

Vitamin B Complex 36mg (B3 - B5 - B6 - B12)
B complex vitamins have been known to be helpful in maintaining the digestive system and insuring proper absorption of food. Helps in utilization of other vitamins, and aids in sodium and potassium balance. As well as helps improve the body's resistance to stress.

(*Dietary Supplement)
LIVE LONG & PROSPER with Fuze Teas

Polyphenols
Powerful Antioxidants that can protect cell membranes and cellular DNA from the damaging effects of free radical induced oxidative damage. Regular consumption of Polyphenols are associated with reduced risk of developing cardiovascular disease and certain cancers.

Click on the bottles below to read nutrition info

Fuze Facts:
The antioxidant capacity in each bottle of FUZE Tea is equal to 3 servings of vegetables.
REFRESHINGLY GOOD FOR YOU!

Vitamin B3
Known to improve circulation and reduce the cholesterol level in the blood. Helpful in maintaining healthy skin and the digestive system.

refresh your soul
with peach mango

Click on the bottles below to read nutrition info

Fuze Facts:
Each bottle of Fuze Refresh has 100% of your Recommended Daily Allowance of essential vitamins and bone building calcium.