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JUN 14 2005

Mr. Alexander P. Hughes
President
MD Drinks, Inc.
901 Tenth Street
Suite 206
Santa Monica, California 90403

Dear Mr. Hughes:

This is in response to your letter of May 27, 2005 to the Food and Drug Administration (FDA) in which you responded to our May 10, 2005 letter concerning statements you were making for your product **FUNCTION URBAN DETOX**.

In our previous letter, we stated that the claim "[B]everage that helps cure and prevent hangovers...." was a claim that did not meet the requirements of 21 U.S.C. 343(r)(6) but rather was a claim that suggested that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. In your letter, you submitted a revised claim that the product "[I]s a physician-developed product that fights hangovers...." We believe that the revised claim continues to be a claim that subjects your product to regulation as a drug.

We believe that you, in part, misunderstand the basis for our objection to your prior claim. The agency's assertion that the claim "[H]elps cure and prevent hangovers....," as well as the revised claim "[I]s a physician-developed product that fights hangovers....," is a disease claim is not based on the use of the verbs "cure" or "prevent," but rather on the fact that product is being represented to be used to treat, cure, mitigate a disease, namely, hangovers. The agency considers alcohol intoxication, and its consequences, to be a disease.

In the preamble to the January 6, 2000 final rule on structure/function claims (65 FR 1000) the agency stated:

"FDA continues to believe that alcohol intoxication, like all poisonings (mushroom, digitalis, or any drug overdose), meets the definition of disease, albeit a transient disease. The definition in Sec. 101.14(a)(5), which FDA is incorporating in this rule, states, in part, that a disease is "damage to an organ, part or structure, or system of the

body such that it does not function properly * * * All poisonings, like alcohol intoxication, cause dose-related dysfunctioning and damage, ranging from mild impairments to death. Alcohol intoxication causes temporary damage to brain function, causing impairments of judgment, attention, reflexes, and coordination. The fact that it is "self-induced" does not remove it from the definition of disease. Deliberate barbiturate overdoses are also self-induced, but clearly meet the definition of disease."

65 FR 1000 at 1011

The revised claim simply changes the verbs "cure" and "prevent" to "fights," yet retains the express intent that the product is intended to be used to minister to a disease (i.e., hangover). Therefore, the revised statement is not a claim subject to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)), but rather a disease claim that suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

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JUN 7 2005

May 27, 2005

Susan J. Walker, M.D.
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

2005-3296

Dear Ms. Walker:

We are writing in response to your letter dated May 10, 2005, in which you indicated that MD Drinks, Inc. (the "Company") may not include the statement "[B]everage that helps cure and prevent hangovers" on its Function Urban Detox dietary supplement. As a result, we have altered the text of the statement on our product to read:

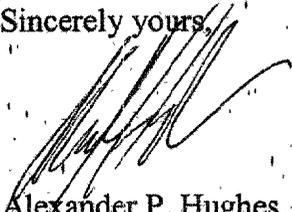
"FUNCTION is a physician-developed product that fights hangovers, helps protect your liver, helps combat the effect of urban pollution on your lungs and sinuses, and boosts your immune system."

Again, the names of the dietary ingredients or supplements that are the subject of the statement are as follows:

- a. Opuntia Ficus Indica
- b. N-acetyl cysteine
- c. Calcium carbonate
- d. Sodium
- e. Ascorbic acid (Vitamin C)
- f. Magnesium oxide
- g. Riboflavin
- h. Vitamin B6
- i. Vitamin B12
- j. Folic acid

Thank you very much, and please do not hesitate to contact me at the above address if you have any additional questions.

Sincerely yours,



Alexander P. Hughes
President, MD Drinks, Inc.