



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

4552 7
AUG 21 P5:12

JUN 12 2007

Mr. Rodney Sacks
Chairman of the Board
Hansen Beverage Company
1010 Railroad Street
Corona, California 92882

Dear Mr. Sacks:

This is in response to your letter of May 23, 2007 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) for the product **Java Monster Coffee + Energy- Big Black Energy Supplement, Java Monster Coffee + Energy- Mean Bean Energy Supplement, and Java Monster Coffee + Energy- Loca Moca Energy Supplement**

21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, a dietary supplement does not include a product represented for use as a conventional food or as a sole item of a meal or the diet (21 U.S.C. 321(ff)(2)(B)). The products identified above appear to be represented for use as conventional foods. They are presented as alternatives to conventional coffees (i.e., "No foam, extra hot, half-caf, no- whip, no-fat, soy latte...Enough of the Coffee House BS already!;" "[H]alf the caffeine of regular coffee, Twice the Buzz!"). They are also described as "premium coffee and cream...supercharged with Monster energy blend." Therefore, in that they appear to be represented for use as conventional foods (i.e., a coffee drinks or beverages), they do not appear to be dietary supplements within the meaning of 21 U.S.C. 321(ff) and claims made for them are not subject to 21 U.S.C. 343(r)(6).

Instead, these products appear to be conventional foods that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, they must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the products in their labeling if they are claims defined by 21 U.S.C. 343(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. Use of a food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market these products as conventional foods and you have any questions about the status of any of their ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

1997S-0163

LET 946

Page 2 - Mr. Rodney Sacks

Please contact us if you require further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph..D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, 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, San Francisco District Compliance, HFR-PA140



HANSEN BEVERAGE COMPANY

Rodney C. Sacks
Chairman of the Board

1010 Railroad Street
Corona, California 92882

951•739-6200
Fax 951•739-6210

May 23, 2007

Certified Mail – Return Receipt Requested

Food & Drug Administration
Office of Nutritional Products
Labeling and Dietary supplements (HFS-810)
Center for food Safety and Applied Nutrition
200 "C" Street, SW
Washington DC 20204



Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21U.S.C.343 (r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21CFR101.93 that Hansen Beverage Company of 1010 Railroad Street, Corona, California 92882, is marketing a dietary supplement bearing the following statement on the label and/or in the labeling:

Text of Claim:

JAVA MONSTER™
COFFEE + ENERGY
ENERGY SUPPLEMENT

No foam, extra hot, half-caf, no- whip, no-fat, soy latte... Enough of the Coffee House BS already!

It's time to get out of the line and step up to what's next

Java Monster ... premium coffee and cream, brewed up with killer flavor, supercharged with Monster energy blend.

Coffee done the Monster way, wide open, with a take no prisoners attitude and the experience and know-how to back it up.

Java Monster half the caffeine of regular coffee, Twice the Buzz!

07-3776

Ingredients that are subject of the claim:

Reduced Fat Milk
Sucrose
Glucose
Taurine
Coffee
Sodium Citrate
Panax Ginseng Root Extract
L-CarnitineAscorbic Acid
Caffeine
Sucralose
Niacinamide
Glucuronolactone
Guarana Seed Extract
Inositol
Pyridoxine Hydrochloride
Riboflavin
Maltodextrin
Cyanocobalamin

Name of Supplement (including brand name):

JAVA MONSTER™ COFFEE + ENERGY - LOCA MOCA
ENERGY SUPPLEMENT

We hereby certify that the information contained in the above notice is complete and accurate, and that Hansen Beverage Company has substantiation that the statements are truthful and not misleading.

Sincerely,

HANSEN BEVERAGE COMPANY

Rodney Sacks
Chairman of the Board



RCS:lhs



HANSEN BEVERAGE COMPANY

Rodney C. Sacks
Chairman of the Board

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2007-3276

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Glucuronolactone
Guarana Seed Extract
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Riboflavin
Maltodextrin
Cyanocobalamin

Name of Supplement (including brand name):

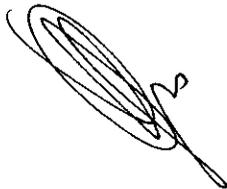
JAVA MONSTER™ COFFEE + ENERGY - MEAN BEAN
ENERGY SUPPLEMENT

We hereby certify that the information contained in the above notice is complete and accurate, and that Hansen Beverage Company has substantiation that the statements are truthful and not misleading.

Sincerely,

HANSEN BEVERAGE COMPANY

Rodney Sacks
Chairman of the Board

A handwritten signature in black ink, appearing to be 'Rodney Sacks', written over a circular stamp or seal.

RS:lhs



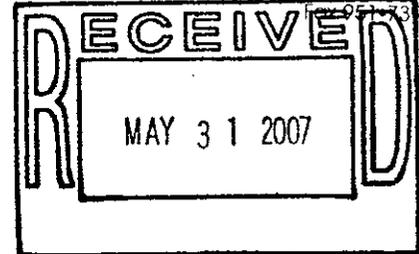
HANSEN BEVERAGE COMPANY

Rodney C. Sacks
Chairman of the Board

1010 Railroad Street
Corona, California 92882

May 23, 2007

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2007-3776

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Name of Supplement (including brand name):

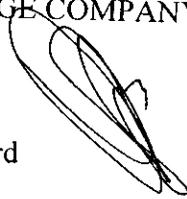
JAVA MONSTER™ COFFEE + ENERGY - BIG BLACK
ENERGY SUPPLEMENT

We hereby certify that the information contained in the above notice is complete and accurate, and that Hansen Beverage Company has substantiation that the statements are truthful and not misleading.

Sincerely,

HANSEN BEVERAGE COMPANY

Rodney Sacks
Chairman of the Board



RCS:lhs