

NEK Products, Inc.
PMB 195
3665 East Bay Dr. Ste. 204
Largo, FL 33771-1965

NEK PRODUCTS, INC.

October 22, 2003

Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition,
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

710 10 10-1
KENDALL A. KEZDI
President
tel: 727-365-5186
ken@thehealthyhangover.com

RECEIVED
10/27/03

Subject: Dietary Supplement Notification: 21 CFR 101.93 and 21U.S.C 343(r)

Dear Madam or Sir:

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act and Food and Drug Administration regulations 21 CFR § 101.93 and 21U.S.C 343(r), this letter is submitted by NEK Products, Inc. as notification to FDA of the below statements made on the labeling of the following dietary supplement product:

(i) Name and Address of Distributor:

NEK Products, Inc.
PMB 195
3665 East Bay Dr. Ste. 204
Largo, FL 33771-1965

(ii) Statements:

"The Healthy Hangover replenishes depleted nutrients. Added antioxidants filter impurities before high levels of the toxin "Acetaldehyde" accumulate."

"The Healthy Hangover contains natural products that are essential to normal daily nutritional intake."

"When consuming an excess of alcohol, vital vitamins and minerals are lost, which are required to process alcohol. When your body becomes deficient this in turn causes hangover symptoms. The Healthy Hangover replenishes these lost nutrients."

"The Healthy Hangover is the healthy way to overcome the common side effects of alcohol."

(iii) Dietary Ingredients/Name of Dietary Supplement:

- **"The Healthy Hangover"**
N-acetyl-cysteine
Vitamin C (as Ascorbic Acid)

975 0162

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13272

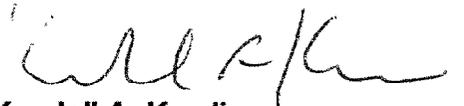
Thiamin (as Thiamin Mononitrate)
Riboflavin
Inositol Hexaniacinate
Vitamin B-6 (as Pyridoxine Hydrochloride)
Pantothenic Acid (as d-Calcium Pantothenate)
Folic Acid
Vitamin B-12 (as Cyanocobalamin)
Biotin (as d-Biotin)

IAW 21 CFR 101.9(c) and 21U.S.C 343(r)(6), product labels and in labeling (e.g., pamphlets, websites), the disclaimer below shall appear on each panel or page where there such is a statement.

“These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”

I, Kendall A. Kezdi, President of NEK Products, Inc., hereby certify that the information contained in the forgoing notice is complete and accurate, and that NEK Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,



Kendall A. Kezdi
President