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JUN 29 2006

Joseph R. Knight
Chief Executive Officer
Nico Worldwide, Inc.
320 Irving Drive
Oxnard, CA 93030

Dear Mr. Knight:

This is in response to your letter of October 19, 2005, 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 (FD&C Act)). Your letter notifies FDA that Nico Worldwide, Inc. is making the following statement in the labeling of a product named Nic Lite™ that you market as a dietary supplement:

Nicotine is a naturally occurring compound in many vegetables including cauliflower, Eggplant, potatoes, and tomatoes. (*New England Journal of Medicine, November 18, 1993, Volume 329, Pages 1581-1582, Copy Attached*) Dietary nicotine may help maintain a healthy smoke free lifestyle.

The subject line of your letter describes this statement as a structure/function claim.

This letter is to advise you that Nic Lite™ does not meet the definition of a dietary supplement. Rather, as explained below, this product is an unapproved new drug whose marketing violates the FD&C Act.

According to your letter, Nic Lite™ contains, among other ingredients, nicotine. Nicotine is an article authorized for investigation as a new drug. 21 U.S.C. 321(ff)(3)(B) states that the term "dietary supplement" does not include "an article authorized for investigation as a new drug...for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food...." Either the finished product or any of its active ingredients may be an article that is "authorized for investigation as a new drug" within the meaning of 21 U.S.C. 321(ff)(3)(B). See *Pharmanex v. Shalala*, 221 F.3d 1151 (10th Cir. 2000).

Nicotine was authorized for investigation as a new drug on December 2, 1987. Substantial clinical investigations have been instituted and the existence of these investigations has been made public. To the best of FDA's knowledge, nicotine was not marketed as a food or dietary supplement before the date nicotine was authorized for investigation as a new drug.

Page 2 - Mr. Joseph R. Knight

The mere presence of nicotine in foods such as cauliflower, eggplant, potatoes, and tomatoes, without any evidence that these foods were promoted for their nicotine content, does not constitute "marketing" nicotine as a food or dietary supplement under 21 U.S.C. 321(ff)(3)(B). See *Pharmanex v. Shalala*, No. 2:97CV262K, 2001 WL 741419 (D. Utah March 30, 2001). Given our understanding that nicotine was not marketed as a dietary supplement or as a food before its authorization for investigation as a new drug, a product that includes nicotine is not a dietary supplement. If you have any evidence to the contrary, please let us know.

An August 27, 2004 letter from your company signed by Philip Mendez, D.O.M., notified FDA of two other labeling claims for Nic Lite™. By identifying your labeling claims for Nic Lite™ as structure/function claims, both that letter and your October 19, 2005 letter concede that this product is intended to affect the structure or function of the body. Because Nic Lite™ is intended to affect the structure or function of the body and is not a dietary supplement, it is subject to regulation as a drug under 21 U.S.C. 321(g)(1)(C).

Nic Lite™ is also a new drug under 21 U.S.C. 321(p) because it is not generally recognized as safe and effective for the uses recommended in its labeling. New drugs may not be legally marketed in the United States without prior approval from FDA (21 U.S.C. 355(a)).

Please contact us if you have any questions regarding this matter.

Sincerely yours,

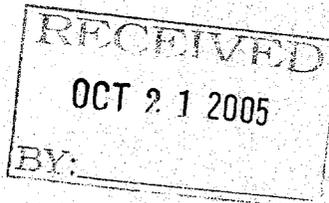


Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Office of Compliance, Center for Drug Evaluation and Research, 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

NICO WORLDWIDE, Inc.
HEALTH PRODUCTS



805/278-9744 • 805/278-9111 FAX • Email: nicoworldwideinc@yahoo.com

October 19, 2005

Office of Nutritional Products
Labeling and Dietary Supplement (HFS-810)
Center for Food Safety and Applied Nutrition
College Park, Maryland 20740

Re: Notification of Structure Function Claim under Dietary Supplement Regulation
21CFR 101.93.

Dear Sir or Ma'am,

In accordance with 21CFR 101.93 (2), below is our notification:

- (i) The name and address of the manufacturer is, packer or distributor that bears this statement is:

Nico Worldwide, Inc. 320 Irving Drive Oxnard California 93030

- (ii) The text of the statement being made is:

**Nicotine is a naturally occurring compound in many vegetables including cauliflower, Eggplant, potatoes, and tomatoes. (*New England Journal of Medicine, November 18, 1993, Volume 329, Pages 1581-1582, Copy Attached*)
Dietary nicotine may help maintain a healthy smoke free lifestyle.**

- (iii) The name of the dietary ingredient or supplement that is the subject of this statement is:

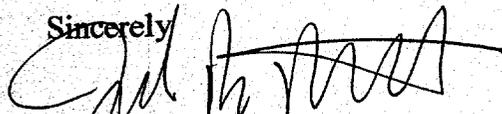
**Nicotine 2 mg per 16 oz in 4 ounce, 8 ounce, 16 ounce 235 mL, 500 mL 1000 mL bottles.
Nicotine 4 mg per 16 oz in 4 ounce, 8 ounce, 16 ounce 235 mL, 500 mL, 1000 mL bottles.**

- (iv) The name of the dietary supplement, including the brand name is:

Nic Lite™

To the best of my knowledge and belief, and based on the information available at the time of execution of this notice, I certify that the information contained in this notice is complete and accurate, and that Nico Worldwide, Inc has substantiation that the statements are truthful and not misleading. **Thank you very much.**

Sincerely

A handwritten signature in black ink, appearing to read "Joe Knight", written over the word "Sincerely".

Joseph R. Knight -CEO
Nico Worldwide, Inc

NICO Worldwide, Inc
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