



JUL 16 2001

8524 '01 AUG -8 P2:21

Robert J. Colclough, III, Esq.
7120 Hayvenhurst Avenue
Suite 206
Van Nuys, California 91406

Dear Mr. Colclough:

This is in response to your letter to the Food and Drug Administration (FDA) dated June 1, 2001, on behalf of NICO International, LLC. Your letter was submitted to FDA pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that NICO International, LLC. is making the following claims, among others, for the product **Nico Sparkling Water**:

- "Quit smoking"
- "You can't afford to smoke"
- "Now you can afford to Quit"
- "Use when you want to smoke less"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely smoking (i.e., an addiction to nicotine). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

The product that is the subject of the notification is named "NICO Sparkling Water." The label of the product also describes the product using the phrase "Just the Taste of Sparkling Water." While the product label bears the statement "A Dietary Supplement" and contains a statement that appears to be intended as the disclaimer required by 21 U.S.C. 343(r)(6) for claims made in labeling of a dietary supplement pursuant to that section (e.g., "This product is not intended to diagnose Treat, Cure or otherwise prevent disease"), this product is not a dietary supplement under the Act because it does not meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff). Therefore, it can not be marketed as a dietary supplement but must instead be marketed as a conventional food. We explain the basis for our conclusion below.

975-0163

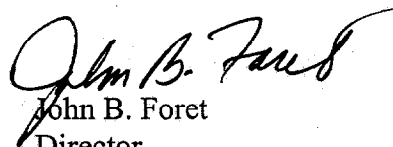
LET 527

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the dietary, and are labeled as a dietary supplement.

Your client's product is represented for use as a conventional food in several ways. First, the product's statement of identity describes the product as water. The product bears nutrition facts labeling. The statement of identity does not identify the product as a "dietary supplement." Therefore, the product is a bottled or drinking water, which is a term that identifies a food that is a standardized food defined in 21 CFR 165.110(a). Therefore, any product represented as such is a conventional food and is not a dietary supplement pursuant to 21 U.S.C. 321(ff)(2)(B) because it is a product being "represented for use as a conventional food." The mere declaration in labeling that a product is a "dietary supplement" does not make the product a "dietary supplement" under 21 U.S.C. 321(ff). Because the product is not a dietary supplement, it must bear nutrition labeling in accordance with 21 CFR 101.9, must comply with the requirements for nutrient content claims (the statement "Contains water and nicotine 4 Mgs." is an unauthorized nutrient content claim) and health claims (if applicable), and may contain only ingredients that are used in accordance with a food additive regulation unless the ingredient are the subject of a prior sanction or are generally recognized as safe (GRAS) among qualified experts for its intended use in foods. We are unaware of a basis to conclude that nicotine is prior sanctioned or GRAS for use in food and it is not an approved food additive.

Please contact us if you have further questions on this matter.

Sincerely,



John B. Foret
Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Page 3 - Mr. Robert J. Colclough, III

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200

FDA, Los Angeles District Office, Compliance Branch, HFR-PA140

Page 4 - Mr. Robert J. Colclough, III

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (Foret)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

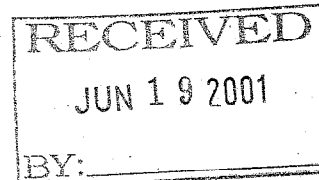
HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:76502.adv:disc59



The Law Offices of
Robert J. Colclough, III
7120 Hayvenhurst Avenue, Suite 206
Van Nuys, California 91406
Telephone: (818) 906-0120
Facsimile: (818) 933-3387

June 1, 2001

VIA U.S. POSTAL SERVICE:

John B. Foret, Director
Food and Drug Administration
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
Washington, D.C. 20204

Re: Submission of labels and other signage for FDA approval pursuant to the Federal Food, Drug and Cosmetic Act

Dear Mr. Foret:

Be advised that this office represents NICO International, LLC in regard to its product Nico Sparkling Water. I am writing this letter pursuant to 21 U.S.C. 343(r)(6) (section 403 (r)(6) of the Federal Food, Drug and Cosmetic Act. The purpose of the correspondence, and the information contained herein and attached hereto, is to inform your office of the truthful, non-misleading nutrient content claims made on the labels placed on each bottle of Nico Sparkling Water.

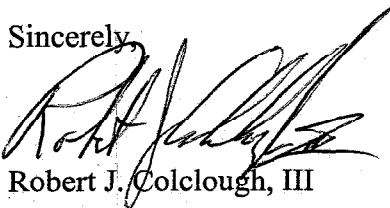
Nico International, LLC makes no claim that Nico Sparkling Water will diagnose, mitigate, treat, cure or prevent a specific disease or class of diseases. Rather, Nico Sparkling Water is simply water with nicotine added at dosages well within regulatory and health guidelines. After reviewing the materials contained herein, it will be shown that no claims are made that suggest that Nico Sparkling Water is intended for drug usage within the meaning of 21 U.S.C. 321(g)(1)(B).

Further, Nico Sparkling Water falls within the definition of a "dietary food supplement" as defined in 21 U.S.C. 321(ff). Nico Sparkling Water simply takes nicotine, a natural extraction from a botanical, and combines it with water. Naturally this product is intended for ingestion as defined in the case United States v. Ten Cartons, et. al., 888 F.Supp.381. This product is designed, intended for and is ingested directly into the gastrointestinal tract thus conforming to the definition set forth by the Court.

This correspondence and the attached materials are intended to put the Food and Drug Administration on actual notice of Nico International, LLC's intentions to go to market with Nico Sparkling Water, marketed as a dietary food supplement. If your office has any comments or questions in regard to anything contained in this letter or the attached materials, please contact this office.

Be advised that Nico International, LLC has several FDA compliant laboratories that have expressed an interest in supplying the nicotine, several more FDA compliant bottlers who will bottle Nico Sparkling Water and a distribution network that is already in place. This is a good faith effort by my client to comply with the Federal Food, Drug and Cosmetic Act. Their intentions are to go to market forty-five (45) days from the date of this correspondence.

Sincerely,



Robert J. Colclough, III

Copies:

FDA: Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200

Enclosures

Mb;hb

Quit Smoking Quit Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

NICO
Distributed under contract for NICO International, LLC Agoura Hills, CA

60250 96000

NICO Sparkling Water

QUIT SMOKING

from **nutripure**

"Just the Taste of Sparkling Water"

Nutrition Facts
Serving Size 500 ml (16.9 oz)
Amount per serving
Calories 0 0%
% Daily Value
Total Fat 0g 0%
Sodium 0mg 0%
Total Carb 0g 0%
Sugars 0g
Protein 0g
Ingredients: Purified Water & Nicotine
*Percent Daily Values are based on a 2,000 calorie diet.
patents pending

- You can't afford to smoke
- Now you can afford to Quit
- Use where you can't smoke
- Use where you shouldn't smoke
- Use when you want to smoke less

- ▶ Must be 18 years or older to purchase
- ▶ Do not use with other Nicotine replacement products
- ▶ Drink no more than 2 bottles per hour
- ▶ Before using, check with your Medical Practitioner, if you have High Blood Pressure, Heart Condition, Pregnant or Lactating
- ▶ For more information read thoroughly the content provided on every six pack
- ▶ A Dietary Supplement. This product is not intended to diagnose Treat, Cure or otherwise prevent disease.

(Contains Water and Nicotine 4 Mgs.) 16 Fl.Oz.

Quit Smoking Quit Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

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60250 96000

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(Contains Water and Nicotine 2 Mgs.) 8 Fl.Oz.

Quit Smoking Quit Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

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(Contains Water and Nicotine 2 Mgs.) 8 Fl.Oz.



FROM
NICO International

YOU MUST BE 18 YEARS
OF AGE TO PURCHASE

**PLEASE READ IMPORTANT INFORMATION ON THE BACK
OF THIS PAGE REGARDING THE USE OF THIS PRODUCT**

Nicotine/Water

**You can't afford to smoke
Now you can afford to Quit
Use where you can't smoke
Use where you shouldn't smoke
Use when you want to smoke less**

**“JUST THE TASTE OF
REFREACHING WATER”**

A copyright, trade marked, patent pending product

Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

PHARMACIST
RECOMMENDED

NICO Sparkling Water



from
nutripure

*"Just the taste
of Refreaching water"*

- You can't afford to smoke
- Now you can afford to Quit
- Use where you can't smoke
- Use where you shouldn't smoke
- Use when you want to smoke less

Distributed under
contract for NICO
International, LLC
Agoura Hills, CA

Bar
Code
Area

Dietary Supplement 16.7 Fl. Oz.
(Contains Water and Nicotine (4Mgs))

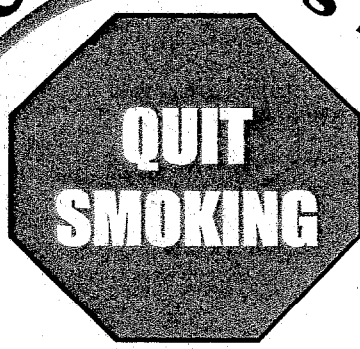
s pending

Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

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Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

FRONT & SIDE Panels FOR 6 Pack

Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

PHARMACIST RECOMMENDED

NICO Sparkling Water

QUIT SMOKING

From
NICO International

"Just the taste of Refreshing water"

- You can't afford to smoke
- Now you can afford to Quit
- Use where you can't smoke
- Use where you shouldn't smoke
- Use when you want to smoke less

patents pending

Dietary Supplement 16.7 Fl. Oz.
(Contains Water and Nicotine (4Mgs))

Distributed under license for NICO International, LLC
Agoura Hills, CA

Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

PHARMACIST RECOMMENDED

NICO Sparkling Water

QUIT SMOKING

From
NICO International

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- For more information read thoroughly the content provided on every six pack
- A Dietary Supplement. This product is not intended to diagnose, Treat, Cure or otherwise prevent disease.

(Contains Water and Nicotine 2 Mgs.) 8 Fl.Oz.

"JUST THE TASTE OF REFRESHING WATER"

Must be 18 years or older to purchase
Do not use with other Nicotine replacement products

Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

PHARMACIST RECOMMENDED

NICO Sparkling Water

QUIT SMOKING

Nicotine/Water

From
NICO International

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Do not use with other Nicotine replacement products

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"JUST THE TASTE OF REFRESHING WATER"

patents pending

Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

PHARMACIST RECOMMENDED

NICO Sparkling Water

QUIT SMOKING

From
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patents pending

Dietary Supplement 16.7 Fl. Oz.
(Contains Water and Nicotine (4Mgs))

Distributed under license for NICO International, LLC
Agoura Hills, CA

Bar Code Area

Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking Quit Smoking

SIDE PANELS
(Tray 24 pack)