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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Rockville, MD 20857

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By Telefax and First Class Mail

William B. Schultz
Carlos T. Angulo
Meredith E. Cabe
Zuckerman Spacder LLP
1201 Connecticut Avenue, NW
Washington, DC 20036

Matthew Myers
William Corr
National Center for Tobacco-Free Kids, Inc.
1400 Eye Street, NW, Suite 1200
Washington, DC 20005

Re: Docket No. 01P-0573

Dear Messrs. Schultz, Angulo, Myers, and Corr and Ms. Cabe:

This responds to your citizen petition,¹ dated December 18, 2001, in which you request that the Food and Drug Administration (FDA):

- Classify and regulate Nicotine Water as a "drug" under the Federal Food, Drug, and Cosmetic Act; or, in the alternative,
- Classify and regulate Nicotine Water as a "food" containing an unapproved food additive under the Act.

¹ The petition was submitted by the National Center for Tobacco-Free Kids, the American Cancer Society, the American College of Preventative Medicine, the American Heart Association, the American Legacy Foundation, the American Lung Association, the American Medical Association, the American Public Health Association, the American Society of Addiction Medicine, the American Society of Clinical Oncologists, the American Thoracic Society, the Latino Council on Alcohol and Tobacco, the National Association of Local Boards of Health, the National Education Association, the Oncology Nursing Society, Oral Health America, National Spit Tobacco Education Program, and the Partnership for Prevention.

01P-0573

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Petition at 2.

As discussed and for the reasons set out below, we grant your petition.

Your petition asserts that S & F Garret sells Nicotine Water over the Internet at www.nicotinewater.com, and that the product contains water and pharmaceutical grade nicotine. Currently, this site offers to sell a product called NICO Water through a company called QuickTest5 ("QT5"). It is unclear whether NICO Water and Nicotine Water are in fact the same product. It appears from the website, for example, that NICO Water contains a slightly different active ingredient, nicotine polacrilex. However, both the website and separate promotional material issued by S & F Garret and the Nicotine Beverage Corporation, which operate www.nicotinewater.com, indicate that the two products are covered by the same patent (U.S. Patent 6,268,386) (see "New Patented Nicotine Beverages for Smoking Cessation, Energy & Weight Loss," at www.prweb.com/releases/2001/8/prweb27201.php (copy attached)), suggesting that the products are identical or that QT5 is a licensee or successor of S & F Garret and/or the Nicotine Beverage Corporation.² In any event, the issues presented by these products are identical for purposes of the following analysis. Thus, we refer to the two products collectively as "Nicotine Water."

Nicotine Water Is Not a Dietary Supplement

You assert in your petition that, notwithstanding the claims made by its manufacturer, Nicotine Water cannot be marketed as a dietary supplement because its active ingredient was first marketed as an approved new drug (Petition at 13-15).

We agree. Section 201(ff)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act ("the Act") expressly states that the term "dietary supplement" does *not* include "an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act" which was not marketed as a dietary supplement or as a food before such approval, certification, or licensing. Here, the principal active ingredient in Nicotine Water is nicotine or nicotine polacrilex. Both are active ingredients in FDA-approved drugs (including Nicoderm CQ, Prostep, Habitrol, and Nicorette). We are unaware of any evidence that either was marketed as a food or dietary supplement before the drugs that contained those active ingredients were first approved. Consequently, Nicotine Water that contains nicotine or nicotine polacrilex as an active ingredient is excluded from the definition of "dietary supplement" under section 201(ff)(3)(B)(i) of the Act. See *Pharmanex v. Shalala*, 221 F.3d 1151 (10th Cir. 2000).

Nicotine Water Is Marketed As a Drug Under the Act

² FDA obtained information about NICO Water and QT5 by accessing the Internet address cited in Tab A of your petition. The Internet site now offers NICO Water sold by QT5, but still references U.S. Patent 6,268,386, which is the same patent cited by S & F Garret and the Nicotine Beverage Corporation for Nicotine Water.

Your petition also maintains that Nicotine Water is a drug under the Act because it is intended to treat or mitigate nicotine addiction (Petition at 5-11) and to affect the structure or function of the body (*id.* at 17, n. 30). In support of this argument, Tab A to your petition contains information and product claims that you downloaded from www.nicotinewater.com. FDA agrees that, as marketed by S&F Garret, the Nicotine Beverage Corporation, and/or QT5, Nicotine Water is a "drug" under the FFDCA.

The manufacturer website materials that you attached to your petition as Tab A include smoking cessation and related claims for Nicotine Water. Specifically, the manufacturer claims that Nicotine Water:

- Is designed for "[p]eople who may or may not wish to quit smoking but cannot smoke at their place of work." (Petition at Tab A; see also "New Patented Nicotine Beverages for Smoking Cessation, Energy & Weight Loss");
- Is designed for "[p]eople who wish to quit smoking" (*id.*);
- "Contains the nicotine equivalent of 2 cigarettes" per bottle (Petition at Tab A); and
- Should not be consumed in quantities greater than "2 bottles per hour. A light smoker may find that it does not even require a full bottle per hour to quench their [sic] need whereas a heavy smoker may require a full 2 bottles per hour." (*Id.*)

S & F Garret and the Nicotine Beverage Corporation also issued marketing materials that describe Nicotine Water as a smoking cessation product:

- "*More effective than the Patch or Gum using Less Nicotine*" (see "New Patented Nicotine Beverages for Smoking Cessation, Energy & Weight Loss" (emphasis added));
- "[a] Method of delivering Nicotine *to reduce use of tobacco products.*" (*See id.* (emphasis added)); and
- "Preferred Nine to one in double blind tests over the Patch & Gum" (*id.*).

Moreover, the patent cited by S & F Garret and the Nicotine Beverage Corporation (in its marketing materials and on its website) and QT5 (on its website) describes Nicotine Water as:

- "A method of delivering nicotine or an alkaloid to an individual *to reduce said individual's use of tobacco products* comprising providing [sic] a beverage with a nicotine or alkaloid having similar physiological activity, the nicotine content being between 0.0001% and 0.1%." (emphasis added)

Section 201(g)(1) of the Act, defines "drug," in part, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and as "articles (other than food) intended to affect the structure or any function of the body." This definition of drug thus turns in large measure on the question of intended use. 21 CFR 201.128 interprets "intended use" as the objective intent of persons legally responsible for the labeling of drugs. It further states that:

The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised...

That the manufacturer may have designated its product as something other than a drug or may have made subjective claims of intent is not determinative. See *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977) ("FDA is not bound by the manufacturer's subjective claims of intent but can find actual therapeutic intent on the basis of objective evidence"); *United States v. Undetermined Quantities of an Article of Drug, Labeled as "Exachol"*, 716 F. Supp. 787, 791 (S.D.N.Y. 1989) (product may be found to be a drug even if its labeling states that it is not a drug); *United States v. An Article . . . Consisting of 216 Individually Cartoned Bottles . . . Labeled in Part: "Sudden Change"*, 409 F.2d 734, 739 (2d Cir. 1969) (fact that an article is a cosmetic does not preclude its being a drug for purposes of the Act); see also *Bradley v. United States*, 264 F. 79 (5th Cir. 1920) (firm shipping mineral water and representing that the water possessed curative or alleviative properties cannot claim that the product was water and not a drug). Therefore, the manufacturer's claims that Nicotine Water is a dietary supplement are not dispositive.

We agree that, as marketed, Nicotine Water is a "drug" as defined by section 201(g)(1)(B) and (C) of the Act. Nicotine addiction has been determined to be a disease (see, e.g., Department of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction, a Report of the Surgeon General*, pages 169-216 (1988)). S & F Garret and the Nicotine Beverage Corporation have promoted and described Nicotine Water as useful in the treatment or mitigation of that disease. Collectively, the claims identified above show that S & F Garret, the Nicotine Beverage Corporation, and QT5 are selling Nicotine Water to help people stop smoking. Accordingly, as marketed, Nicotine Water is a drug within the meaning of sections 201(g)(1)(B) and (C) of the Act.³

³ The definition of drug in section 201(g)(1)(C) of the Act expressly excludes food. However, neither Nicotine Water itself nor the nicotine and nicotine polacrilex ingredients are food within the meaning of 201(g)(1)(C) of the Act because they are not being consumed for their taste, aroma, or nutritive value. See *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335 (7th Cir. 1983). Indeed, U.S. Patent 6,268,386, which S & F Garret cites throughout its promotional material and QT5 cites on www.nicotinewater.com, states that the nicotine/water ratio in Nicotine Water is based, in part, on "a fluid amount sufficient to mask as much as the nicotine taste as reasonable"

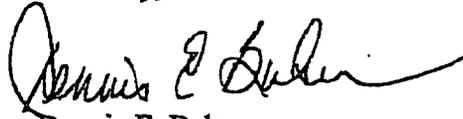
Based on the smoking cessation and related claims identified in Tab A to your petition, Nicotine Water is also a "new drug" within the meaning of section 201(p) of the Act because no one has submitted to FDA any information to show that it is generally recognized among qualified experts as safe and effective for its suggested uses. Under sections 505(a) and 301(d) of the Act, a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved New Drug Application (NDA) is in effect for that drug⁴.

Conclusion

For the reasons stated above, we agree that:

- Nicotine Water is not a dietary supplement;
- As marketed, Nicotine Water is a drug; and
- As marketed, Nicotine Water is a new drug and an unapproved new drug.

Sincerely,



Dennis E. Baker

Associate Commissioner for Regulatory Affairs

(emphasis added). Unlike a food, Nicotine Water is also sold with suggested dosing information that varies depending on whether a person is a light or heavy smoker. In addition, foods do not typically compare themselves to FDA-approved drugs in terms of product efficacy. As noted, some marketing material for Nicotine Water suggests that the product is more effective for smoking cessation than nicotine patches or gum. Finally, S & F Garret states in its promotional material that Nicotine Water "should not be part of a regular dietary program"—in other words, Nicotine Water is not to be used as a food.

⁴ Since the agency agrees that, as marketed, Nicotine Water is a drug and an unapproved new drug, we need not consider at this time whether the product would be adulterated if regulated as a food.