

IN THE FOOD AND DRUG ADMINISTRATION

**Petition for Regulation of
S & F Garret's Nicotine Water**

Docket No. _____

Submitted on Behalf of the National Center for Tobacco-Free Kids, the American Cancer Society, the American College of Preventive 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.

DECEMBER 18, 2001

Citizen Petition

This is one of four petitions submitted to the Food and Drug Administration (“FDA”) today by the National Center for Tobacco-Free Kids, the American Cancer Society, the American College of Preventive 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. The other petitions concern Ariva tobacco lozenges, OMNI and Advance “low carcinogen” cigarettes, and Eclipse. Each petition urges FDA to regulate a product that is being marketed to users of traditional tobacco products as a safer, healthier way of consuming tobacco or nicotine, or both.

Although the Supreme Court held last year that the FDA does not have jurisdiction over traditional tobacco products as customarily marketed, the Court left undisturbed the agency’s jurisdiction over (1) nicotine-containing products other than traditional tobacco products and (2) traditional tobacco products that make drug claims. In the case of Nicotine Water, which is the subject of this petition, a manufacturer has taken water and added nicotine. Nicotine is used as a pesticide and has been shown to be hazardous. Nicotine is not approved as a food additive, nor is it on the GRAS list of additives that are authorized for use in food products. The addition of nicotine has only been approved for use in OTC and prescription drug smoking cessation aids. That approval was predicated on agency premarket review of the results of required testing by the manufacturer of the precise dose and the precise product to be sold. Yet the manufacturer of

Nicotine Water are marketing this product without first submitting it for approval to FDA and without going through any government review to verify its safety when added to this product. As we demonstrate in this petition, Nicotine Water is in fact subject to various requirements of the Federal Food, Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 301 *et seq.*, as traditionally interpreted by the agency and the courts. Therefore, the FDA should grant this petition and prohibit the sale of Nicotine Water until its manufacturer has complied with the law.

Nicotine Water

S & F Garret (“Garret”) sells Nicotine Water over the Internet. Nicotine Water is nothing more than regular bottled water plus an amount of nicotine equal to what the manufacturer claims would be found in two cigarettes.¹ Garret claims Nicotine Water is designed to provide a source of nicotine to individuals that is safer than conventional tobacco products, and that can be used by smokers who are either unable to smoke in particular settings or who wish to quit altogether.

A. Action Requested

Petitioners request that the FDA require premarket approval of Nicotine Water under the FFDCA. Specifically, this petition requests that the FDA classify, and therefore regulate, Nicotine Water as a “drug” within the meaning of the FFDCA, or, in the alternative, that FDA classify and regulate Nicotine Water as a “food” containing a hazardous, unapproved food additive under the FFDCA.

¹ <http://www.nicotinewater.com/> (last visited December 10, 2001). The materials on this Internet site are Attachment A to this petition.

B. Statement of Grounds

As noted above, Garret claims Nicotine Water is designed to provide an alternative source of nicotine to individuals who are unable to smoke in particular situations – in the workplace or on a plane, for example – as well as to those individuals who “wish to quit smoking.”² Garret also touts the product’s possible health-related advantages, noting that it “gives cigarette users an alternative source of Nicotine that is free of the severe health risks of tar and smoke.”³ Garret continues: “What is most important [about Nicotine Water] is what [the product] does not contain. It does not contain tar and smoke which are substances so potent that they not only kill 400,000 cigarette smokers per year, they also, though second-hand smoke, kill an additional 53,000 individuals.”⁴

When companies have previously attempted to market nicotine-containing products in any form other than conventional cigarettes, pipe tobacco, cigars, or traditional forms of snuff and chewing tobacco, FDA has consistently determined that these products must be pre-approved under the FFDCFA. Indeed, FDA has never officially permitted the marketing without Agency approval of unconventional nicotine-containing products of any kind because of the addictive and potentially harmful effect of nicotine. While Garrett does not describe the source of the nicotine in Nicotine Water, in all probability, it is extracted from tobacco.

For purposes of the applicability of the FFDCFA, there is no difference between Nicotine Water and nicotine replacement products (such as nicotine gum or Masterpiece Tobacs) that the agency has previously decided to regulate. Like nicotine replacement gum and Masterpiece

² *Id.*

³ *Id.*

⁴ *Id.*

Tobacs, Nicotine Water will be marketed as a source of nicotine for people to use to address symptoms of nicotine addiction, and, despite the presence of nicotine, it will be sold in food form. Nicotine Water therefore falls squarely within FDA’s regulatory authority under the FFDCFA. If the Agency fails to exercise its authority over this product, it will in essence be giving any manufacturer of any substance chewed, eaten or otherwise consumed the license to add addictive and uncontrolled doses of nicotine to any product.

Garret claims otherwise, arguing that Nicotine Water is a “dietary supplement” that, under the provisions of the Dietary Supplement Health and Education Act (“DSHEA”)⁵, need not be pre-approved under the FFDCFA. Garret makes this claim on the grounds that Nicotine Water “was conceived as a healthier alternative to cigarettes and other tobacco products and not as a treatment or cure for the use of tobacco products.”⁶

In Section 1 of this Petition, we demonstrate that FDA should, consistent with its regulation of nicotine replacement gum and similar products, classify and regulate Nicotine Water as a “drug” under the FFDCFA. In the alternative, as demonstrated in Section 2, FDA should regulate Nicotine Water as a food. In Section 3, we explain why, contrary to Garret’s claims, the company cannot escape FDA oversight by claiming that Nicotine Water is a dietary supplement. And finally, in Section 4 we discuss why FDA regulation of Nicotine Water is not foreclosed by the United States Supreme Court’s decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

⁵ DSHEA has been codified as part of the FFDCFA.

⁶ Attachment A.

1. Nicotine Water is a “drug” for purposes of the FFDCA.

The FFDCA defines “drug” to include “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body.” 21 U.S.C. §§ 321(g)(1)(B), 321(g)(1)(C). Nicotine Water qualifies under the FFDCA as a drug for two independent reasons. First, Nicotine Water, like other nicotine-substitution products, is intended to deliver nicotine to the user to mitigate, or temporarily to treat, nicotine addiction. Second, Garret has made claims about the potential health benefits of using Nicotine Water rather than traditional tobacco products that FDA has previously said constitute “drug claims” such that the product should be regulated as a drug.

a. Nicotine Water is intended temporarily to treat or to mitigate the disease of nicotine addiction.

It is widely recognized that nicotine addiction is a disease.⁷ FDA has approved several products, including the nicotine patch, nicotine gum, and the nicotine inhaler, as drug treatments for nicotine addiction. Those products deliver nicotine to people who are addicted to that drug, but who do not want to smoke cigarettes or use smokeless tobacco products.⁸

Garret’s own statements about Nicotine Water confirm that the product is intended for those who are addicted to nicotine. Garret has claimed that its product is an “alternative source

⁷ World Health Organization, 3 *International Statistical Classification of Diseases and Related Health Problems* 537 (10th rev. 1994); American Psychiatric Ass’n, *DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders* 264-65 (4th ed., text rev. 2000); *see also* Office on Smoking and Health, Department of Health and Human Services, “The Health Consequences of Smoking: Nicotine Addiction, a Report of the Surgeon General” (1988) (hereinafter “Surgeon General’s Report”), *available at* http://www.cdc.gov/tobacco/sgr_1988.htm.

⁸ *See, e.g., The Science of NRT (Nicotine Replacement Therapy)*, *available at* http://www.nicorette.com/nicr_internal/nrt4.html (last visited December 10, 2001) (Attachment B).

of nicotine”⁹ that is directed at “hard-core smokers [who] may need nicotine medications for years to control their craving.”¹⁰ And the categories of individuals that Garret claims will be the primary consumers of Nicotine Water are people who cannot use, or wish to stop using, traditional nicotine delivery products like cigarettes.¹¹ Garret says it has marketed Nicotine Water to individuals who are users of nicotine-delivery products. The makers of Nicotine Water claim that they anticipate that the people who will buy its product are primarily people who use, or are addicted to, nicotine, but there is nothing to prevent others from purchasing and using the product. Garrett says that the purpose of the product is to allow someone who is addicted to nicotine to avoid withdrawal symptoms.

Nicotine Water is therefore functionally analogous to nicotine-substitution products, like nicotine gum, that were created to serve the same purpose and are regulated by the FDA as drugs. The only apparent difference is that other nicotine-substitution products are intended as, and marketed as, permanent solutions to nicotine addiction (“cessation aids”), while Garret markets Nicotine Water as a temporary, situation-specific treatment. The distinction is irrelevant to a determination of whether Nicotine Water is intended for use in treatment *or mitigation* of a disease under the FFDCA.¹² Cough syrup, for example, is a temporary treatment of the

⁹ Attachment A.

¹⁰ Jacob Sullum, “Nicotine Fixes,” *Reason Online*, June 28, 2001 (quoting unidentified Garret source).

¹¹ These groups include “(1) People who may or may not wish to quit smoking but cannot smoke at their place of work; (2) People who wish to quit smoking; (3) Commuters/travelers [who travel in] planes, trains, buses and car-pools; (4) People who work in [p]ublic and government buildings where smoking is not allowed; [and] (5) Parents not wishing to expose their children to tobacco smoke.” Attachment A.

¹² And in any event, there are indications that Garret does in fact intend Nicotine Water to serve as a smoking cessation aid, not simply as a temporary, situation-specific treatment of nicotine

symptoms of a disease, but is no less a drug because it is not intended as a permanent cure.

Nicotine Water was developed for the same disease as nicotine-substitution products, to achieve an analogous effect, and should be regulated as a drug.

Garret has avoided comparisons to other nicotine-substitution products, asserting its product is not a drug, but rather a dietary supplement.¹³ What Garret chooses to call its product, however, does not determine whether its product is subject to the requirements applicable to new drugs.¹⁴ Analysis of “intended use” under the FFDCA is not limited to the manufacturer’s explicit statements or marketing strategy. FDA may ascertain actual intent on the basis of relevant objective evidence as well.¹⁵ As the regulations implementing the FFDCA provide, “intent . . . may be shown by the circumstances surrounding the distribution of the article It may [also] be shown by the circumstances that the article is . . . being offered and used for a purpose for which it is neither labeled nor advertised.” 21 C.F.R. §201.128.¹⁶

addiction. *See Beverage Industry*, August 8, 2001 (“[A] company called S&F Garret says it is looking to license nicotine beverages *to compete with the nicotine patches currently on the market to help smokers quit smoking.*”) (Emphasis added). FDA should inquire further into whether Garret, in fact, intends Nicotine Water to compete with regulated smoking cessation aids.

¹³ Attachment A.

¹⁴ We specifically address below, at pp. 13-17, Garret’s claim that Nicotine Water is a dietary supplement.

¹⁵ *National Nutritional Foods Ass’n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977).

¹⁶ Courts have held that evidence of consumer use is relevant in determining a product’s “intended use.” *National Nutritional Foods Ass’n v. Mathews*, 557 F.2d at 334 (FDA may determine intent from relevant objective evidence, including consumer use); *Action on Smoking & Health v. Harris*, 655 F.2d 236, 239-240 (D.C. Cir. 1980) (consumer use can be relevant in determining manufacturer intent).

FDA has concluded that a manufacturer's intent under the FFDCa can be inferred when a reasonable person in the position of the manufacturer would foresee that the product will be used in a certain way (to treat or mitigate a disease) or will have certain effects (in this case, pharmacologic effects on the structure or function of the body).¹⁷ That Nicotine Water will be used by consumers as a temporary treatment for, or to mitigate, nicotine addiction is clear. It is not only foreseeable to Garret; it is evident in the company's own statements about the product. Thus, it is clear Nicotine Water is "intended" to treat or mitigate a disease for purposes of the FFDCa.

Further, and perhaps more significantly, whether or not Garret chooses to advertise it as such, it bears repeating that its product is functionally similar to products like nicotine gum or the nicotine patch, which are regulated as drugs by FDA. The marketing of products like Nicotine Water heralds "the emergence of a market not for tobacco, but for nicotine."¹⁸ Failing to regulate that product as other nicotine-substitution products are regulated would sanction the selling an equivalent product without any requirement that the product be found safe and effective by the FDA.

b. Garret has made health claims concerning Nicotine Water.

FDA has consistently interpreted the FFDCa to include as "drugs" products that claim, or are intended, to confer health benefits to consumer, and, consistent with the FFDCa's text,

¹⁷ Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,690 (Aug. 28, 1996) (Final Rule). Although that regulation is no longer in effect since the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*, *supra*, the Court did not address or rule on FDA's analysis of "intended use" under the FFDCa. 529 U.S. at 131-32.

¹⁸ Gordon Fairclough, "'Cigarette' Mints Target Customers Who Want Alternative to Cigarettes," *Wall Street Journal*, April 27, 2001.

has defined health claims to include both affirmative claims and claims of reduced risk.¹⁹ The manufacturers of Nicotine Water make health claims with respect to that product. As discussed above, Garret’s promotional and marketing materials expressly suggest that Nicotine Water users are less likely than conventional cigarette smokers to develop diseases normally associated with smoking. *See* Attachment A.

Garret suggests in its promotional materials that the company’s claim that Nicotine Water is a “healthier alternative” to smoking is distinct from a claim that Nicotine Water is “a treatment or cure for the use of tobacco products.” Attachment A. Put simply, Garret is claiming that there is a difference between “reduced-risk” claims of the kind it is making with respect to Nicotine Water, and health claims that confer drug status on a product. The FDA has rejected this argument, and should do so again.

First, treating so-called reduced-risk nicotine products as “drugs” under the FFDCA is consistent with the statutory text because such products are intended to be used to mitigate or prevent diseases associated with smoking. As discussed above, most smokers are addicted to nicotine, and these smokers are the target audience for Nicotine Water. Reduced-risk products like Nicotine Water are designed to furnish smokers who are addicted to nicotine with an alternative, “healthier” delivery system for that drug, and thereby to mitigate or prevent diseases associated with the traditional delivery system for nicotine – *i.e.*, cigarettes. The courts have

¹⁹ *See, e.g., United States v. 46 Cartons*, 113 F. Supp. 336 (D.N.J. 1953); *United States v. 354 Bulk Cartons*, 178 F.Supp. 847 (D.N.J. 1959); Hearings on S. 1454 Before the Consumer Subcommittee, Senate Committee on Commerce, 92nd Cong. 240 (1972) (stating FDA position that cigarettes claiming beneficial physical effects are drugs under FFDCA); Health Consequences of Smoking: Nicotine Addiction: Hearing Before the Subcommittee on Health and the Environment, House Committee on Energy and Commerce, 100th Cong. 17 (1988) (same). A food that makes such health claims is not regulated as a drug so long as it complies with the requirements of 21 U.S.C. § 343(r). 21 U.S.C. § 321(g)(1). This exception does not apply here.

held that the FDCA's definition of drug should be liberally construed in order to effectuate the public health goals of the statute. *United States v. Article of Drug Bacto-Unidisk*, 394 U.S. 784, 792 (1969); *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 701-02 (2d Cir.), *cert. denied*, 423 U.S. 827 (1975). Treating reduced-risk products like Nicotine Water as drugs is therefore the proper construction of the FDCA.

Second, FDA has previously evaluated claims of potential health benefits associated with alternative nicotine delivery systems, and concluded that a product bearing those claims would be a "drug" for purposes of the FDCA. In 1997, Star Scientific, Inc., proposed to sell a chewing gum called "GumSmoke" that contained tobacco. Star made claims about the safety of the product that were similar to claims Garret has made about Nicotine Water:²⁰ "gum for smokers," "when you can't smoke," and "the alternative you need." Star also issued a press release that suggested that GumSmoke would contain specially processed tobacco that was "TSNA-free."²¹ FDA objected, concluding that Star's presentation of GumSmoke could create the perception that it was a "milder, safer form of smokeless tobacco, or a milder, safer substitute for smoking conventional cigarettes."²² FDA noted further that "any representations that the use of this product as an alternative to tobacco may prevent or mitigate diseases associated with tobacco use, would be regarded by the agency as 'drug' claims under section 201(g)(1) of the

²⁰ Letter from Kevin Budich, Compliance Officer, Center for Drug Evaluation and Research, FDA, to Paul L. Perito, then-outside counsel for Star Scientific (July 22, 1998) (Attachment C).

²¹ *Id.* "TSNA" stands for "tobacco-specific nitrosamine," a known carcinogen.

²² *Id.*

[FFDCA, 21 U.S.C. § 321(g)(1)] and any such representations would cause this product to be a ‘new drug’ under section 201(p) of the Act [21 U.S.C. 321(p)].”²³

Garret is also claiming that Nicotine Water is a “safer substitute for smoking conventional cigarettes.” Indeed, Garret’s promotional materials for Nicotine Water specifically draw comparisons between the relative safety of Nicotine Water and cigarettes, and conclude that the former is the “healthier alternative.”²⁴ Thus, like GumSmoke, Nicotine Water is expressly intended “for use in the mitigation . . . or prevention” of diseases associated with smoking. 21 U.S.C. § 321(g). Nicotine Water falls within the FFDCA’s definition of “drug” and is subject to regulation by FDA.

Third, Garret’s distinction makes no sense as a matter of public policy. Consumers are as likely to be misled by claims of relative safety as they are by claims of affirmative health benefits. This is especially true in the tobacco/nicotine context, where smokers who are addicted to nicotine are looking for a relatively safe way to satisfy that addiction and are likely to rely on claims that a particular nicotine delivery system reduces the risks associated with smoking. Garret cannot dispute that its claims regarding Nicotine Water are designed to convince consumers of the relative health benefits of using its product. FDA can, and should, regulate Nicotine Water on the basis of these claims.²⁵

²³ *Id.*

²⁴ Attachment A.

²⁵ The fact that Nicotine Water has been marketed as a dietary supplement does not change its status as a drug under the FFDCA. A product for which health claims are made is a “drug” under that statute regardless of whether it is labeled as such. *See, e.g., United States v. 46 Cartons*, 113 F.Supp. at 337 (“If there be an indication of intent to use the article for the cure or mitigation, or treatment or prevention of disease in man, then clearly the subject matter of the libel is to be considered a drug within the meaning of the [FFDCA]”); *FDA Overview of Dietary Supplements*, available at <http://www/cfsan.fda.gov/dms/ds-oview.html> (last visited November

2. Under the FFDCA, Nicotine Water is a “food” containing a “food additive”.

Even if Nicotine Water were not a drug, it is a “food” containing nicotine as a “food additive” under the FFDCA, and is therefore subject to FDA regulation under the FFDCA’s food additive provisions. 21 U.S.C. § 348.²⁶

Under the FFDCA, “food” is defined as, *inter alia*, “articles used for food or drink for man or other animals.” 21 U.S.C. § 321(f). There is no question that bottled water falls within this definition. Similarly, a “food additive” under the FFDCA is “any substance the intended use of which results or may reasonably be expected to result . . . in its becoming a component or otherwise affecting the characteristics of any food. . . .” 21 U.S.C. § 321(s). Nicotine was clearly intended by Garret to be a component of its Nicotine Water product, and therefore meets this definition.

FDA has already treated as a food additive a product containing nicotine, Masterpiece Tobacs.²⁷ Masterpiece Tobacs was a gum that contained tobacco. The product was labeled as a tobacco product, and its manufacturer sought to have it treated as smokeless tobacco. Analyzing the form of the product and the way it was to be used, FDA concluded it was gum – made like

12, 2001) (hereinafter *Overview of Dietary Supplements*) (“[A] product sold as a dietary supplement and promoted on its label as a treatment, prevention, or cure for a specific disease or condition would be considered an unapproved – and thus illegal – drug.”)

²⁶ Though, as outlined above, Nicotine Water would most appropriately be regulated as a drug, the definitions of “food” and “drug” are not mutually exclusive under the FFDCA. Products may be foods but still be used, and regulated, as drugs. *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 336 (7th Cir. 1983).

²⁷ Letter from Richard J. Ronk, Acting Director, Center for Food Safety and Applied Nutrition, Department of Health and Human Services, to Stuart Pape, attorney for Pinkerton Tobacco Co. (Sept. 16, 1987) (Attachment D); Letter from John M. Taylor, Associate Commissioner for Regulatory Affairs, Department of Health and Human Services, to Stuart Pape, attorney for Pinkerton Tobacco Co. (April 12, 1998) (Attachment E).

gum and designed to be used like gum – but with an added ingredient that constituted a food additive under the FFDCA. The analysis of Nicotine Water should be no different. Nicotine Water, like Masterpiece Tobacs, is made like a food and is designed to be consumed like a food. And the nicotine in Nicotine Water, like the tobacco in Masterpiece Tobacs, is a food additive to be regulated under the FFDCA. The fact that Nicotine Water will have a added effect to that provided by most foods – that of providing its consumers with nicotine – does not alter its status as food. “Foods” need not necessarily be articles used solely for taste, aroma, or nutritive value. *Nutrilab v. Schweiker*, 713 F.2d at 338.²⁸

A food additive is deemed unsafe – and the food in which the additive appears is considered “adulterated” -- under the FFDCA unless there is a regulation in effect prescribing the conditions under which the additive may be safely used. 21 U.S.C. § 348(a). A manufacturer seeking such a regulation may file a food additive petition with FDA. 21 U.S.C. § 348(b). Given that its product meets the relevant definitions in the FFDCA, Garret must file such a petition with respect to Nicotine Water. As marketed, Nicotine Water must be categorized as an adulterated food.

3. Garret cannot escape FDA regulation by claiming Nicotine Water is a dietary supplement.

As noted above, Garret seeks to avoid FDA’s regulation of Nicotine Water as either a food or a drug by claiming that its product is a dietary supplement, and therefore subject to the less stringent regulatory regime set forth for those products under the DSHEA. This claim does not shield Nicotine Water from FDA pre-approval requirements, for several independent reasons.

²⁸ That Nicotine Water functions as a nicotine source, however, shows that the product would be more appropriately regulated as a drug, as explained above.

a. Nicotine Water is not a dietary supplement because its active ingredient was first marketed as a drug.

When Congress enacted the DSHEA, it was concerned that active drug ingredients would be marketed as dietary supplements in order to escape FDA regulation. In response to this concern, Congress exempted from the DSHEA’s definition of dietary supplements “article[s] . . . approved as a new drug under [21 U.S.C. § 355] . . . which w[ere] not before such approval . . . marketed as a dietary supplement or as a food unless the Secretary, in the Secretary’s discretion, has issued as regulation . . . finding that the article would be lawful under this Act.” 21 U.S.C. § 321(ff)(3)(B)(i).

Nicotine, the principal active ingredient of Nicotine Water, is clearly “an article . . . approved as a new drug” under 21 U.S.C. § 355. FDA has regulated and approved as new drugs under that section a string of products containing nicotine as *their* principal active ingredients – nicotine gum, the nicotine patch, and the nicotine inhaler among them. Further, insofar as we can determine, prior to such approval of these nicotine products, nicotine was not marketed as a dietary supplement or as a food. Nicotine Water therefore falls squarely within the DHSEA’s exception, and outside that statute’s definition of a dietary supplement. It must therefore be regulated as a food or drug under the FFDCFA.

That nicotine is only a principal ingredient of Nicotine Water, rather than the finished drug product itself, does not change the equation. FDA has determined that “an article” refers not only to a finished product, but also to constituent components of that product, and the courts have upheld this reading of the statute. Thus, if a product claiming to be a dietary supplement contains as one of its ingredients a substance that was approved as a new drug under the FFDCFA, but that was not marketed as a food or a dietary supplement prior to such approval, the product is not a “dietary supplement” for purposes of the DSHEA.

The Tenth Circuit’s decision in *Pharmanex v. Shalala*, 221 F.3d 1151 (10th Cir. 2000), is directly on point, and compels the conclusion that Nicotine Water is not a dietary supplement. There, the Court of Appeals agreed with FDA that the product Cholestin was not a dietary supplement, upholding the Agency’s determination that because Cholestin’s principal active ingredient, lovastatin, was also the principal active ingredient in the prescription drug Mevacor, Cholestin fell within the DSHEA’s exception for “articles . . . approved as new drugs.” In reaching this conclusion, the Tenth Circuit reasoned that if the DSHEA exception only applied to finished drug products, a dietary supplement manufacturer could simply combine the principal active ingredient of a prescription drug with some other ingredients, and market the equivalent of a prescription drug as an unregulated dietary supplement. To permit this subterfuge, the court of appeals emphasized, “would contravene one of the primary objectives of the [FFDCA], namely to ensure that any product regulated by the FDA is safe and effective for its intended use.” 221 F.3d at 1159 (internal quotations, citations omitted).

In marketing Nicotine Water, Garret is attempting to do precisely what the Tenth Circuit and FDA held the manufacturer of Cholestin *could not do* under the DSHEA— that is, combine an active ingredient of an FDA-approved drug with some additional ingredients in order to escape FDA regulation. FDA recognized in *Pharmanex* that such efforts were inconsistent with the public health, and it should do so again here.

- b. Even if Nicotine Water were a dietary supplement, it would be subject to FDA regulation because its manufacturer has not complied with the requirements for dietary supplements containing new dietary ingredients.**

While dietary supplements may generally be marketed without prior FDA approval, a different regime exists for supplements that contain a “new dietary ingredient.” A supplement containing such a “new dietary ingredient” is deemed “adulterated,” and therefore banned from

the market absent FDA regulation, if “there is inadequate information to provide reasonable assurance that” the new ingredient is safe. 21 U.S.C. § 342(f). The DSHEA elaborates on the “adulteration” test for dietary supplements containing new dietary ingredients:

A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under [the FFDCA] unless . . .

- (1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.
[or]
- (2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information . . . which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

21 U.S.C. § 350b. The DSHEA provides for a manufacturer of a dietary supplement to submit a petition to FDA seeking the issuance of an order by the Agency prescribing the conditions under which a new dietary ingredient may be safely used. *Id.*

Nicotine Water apparently contains a new dietary ingredient – nicotine –²⁹ for which there is inadequate information regarding its safety under the conditions prescribed for its use on the Nicotine Water label. To Petitioners’ knowledge, nicotine has never been present in the food

²⁹ According to the DSHEA, a “new dietary ingredient” is defined as a “dietary ingredient that was not marketed in the United States before October 15, 1994.” 21 U.S.C. § 350b. FDA has determined that a substance qualifies as a “dietary ingredient” if it is, among other things, a “botanical.” *See Overview of Dietary Supplements, supra* n.25. Nicotine is derived from plants and is therefore a botanical. And to Petitioners’ knowledge there is no evidence that nicotine was marketed as a dietary ingredient prior to 1984.

supply as an article used for food. Nor to Petitioners' knowledge has Garret presented any evidence demonstrating that consumption of nicotine under the conditions set forth on the Nicotine Water label "will reasonably be expected to be safe." Under these circumstances, Nicotine Water must be deemed "adulterated" under the FFDCA, and Garret may not market that product absent an FDA regulation prescribing the conditions under which it may be safely used.³⁰

4. The Supreme Court in *Brown & Williamson* preserved FDA's authority to regulate products like Nicotine Water.

Whether FDA treats Nicotine Water as a drug, food, or dietary supplement containing a new dietary and previously unapproved ingredient, it is imperative that the Agency assert jurisdiction over this product in order prevent the use of nicotine in food products without prior approval of the Agency and to evaluate the safety of Nicotine Water.

The Supreme Court's *Brown & Williamson* decision does not indicate otherwise. In that case, the Court held that FDA does not have jurisdiction to regulate *conventional tobacco products as customarily marketed*. The Court invalidated an FDA regulation asserting jurisdiction over traditional cigarettes and smokeless tobacco products, finding that Congress had not granted FDA authority over traditional tobacco products as customarily marketed. Among

³⁰ We note further that even if Nicotine Water is a dietary supplement that does not include a "new dietary ingredient," it may still be regulated as a drug under the FFDCA if there is evidence other than the supplement's labeling to indicate that it affects the structure or function of the human body. *United States v. Undetermined Quantities of Articles of Drug*, 145 F.Supp.2d 692, 698 (D. Md. 2001); *United States v. Ten Cartons*, 72 F.3d 285, 287 (2d Cir. 1995) (per curiam). There is ample scientific evidence to demonstrate that Nicotine Water is intended to affect the structure or function of the human body. *See generally* "Surgeon General's Report," *supra* n.7. Equally clearly, that effect was intended by the product's manufacturer, as demonstrated by Garret's marketing materials (*see* Attachment A). Consumers will use Nicotine Water as a source of nicotine, a substance they seek precisely because of its effects on the structure or

the reasons cited by the Court for the conclusion that Congress had not intended to grant FDA authority over traditional tobacco products was that Congress had enacted legislation concerning tobacco inconsistent with the Court's view that if FDA asserted jurisdiction over traditional tobacco products, the agency would be required to ban the sale of those products. 529 U.S. at 137-139.

Brown & Williamson does not prevent FDA from regulating Nicotine Water, for three reasons. First, the Court's opinion focused on FDA's 1996 jurisdictional statement, in which the Agency reversed its longstanding position that it should not regulate *traditional cigarettes and smokeless tobacco products*. 529 U.S. at 125 (citing 61 Fed.Reg. 44,619 - 45,318). Quite clearly, Nicotine Water is not a tobacco product, much less a *traditional* tobacco product, and in fact, has much more in common with nicotine substitution products under FDA jurisdiction than with conventional cigarettes. There is no evidence that Congress intended to exempt from regulation a broad range of products that do not bear the characteristics of traditional tobacco products then on the market.

Second, the Court's holding did not affect FDA's longstanding authority to regulate as drugs any product bearing health claims. Rather, the *Brown & Williamson* Court concluded that Congress had effectively ratified FDA's prior interpretation of its own authority, 529 U.S. at 158-59, which historically included, and continues to include, FDA regulation of tobacco and nicotine products bearing health claims. As outlined above, Garret has made explicit and implicit health claims about Nicotine Water that bring it within FDA's jurisdiction and outside the scope of *Brown & Williamson*.

function on the body. There is no other reason for adding nicotine to water. Nicotine Water should therefore be regulated as a drug under the FFDCFA.

Third, central to the Court's holding in *Brown & Williamson* was its conclusion that FDA regulation of the traditional tobacco products at issue would necessarily lead to a ban on conventional tobacco products as customarily marketed, which the Court held that Congress did not intend. Granting this petition will not result in a ban on conventional tobacco products. Rather, it will simply place on Garret seeking prior approval of the agency before adding an unapproved, harmful ingredient like nicotine to its products without first seeking the approval of the Agency. Thus, FDA regulation of Nicotine Water is in no way inconsistent with Congress' intent, and continues to be within the Agency's authority

* * *

At the present time, there is no evidence before FDA to demonstrate that Nicotine Water is a safe product. Clearly, *the product must be subjected to Agency scrutiny before any conclusions are drawn as to the product's safety, and before Nicotine Water becomes widely available in the market.*

This approach is consistent with Agency practice regarding other substitutes for conventional tobacco products. FDA has regulated the nicotine patch, nicotine gum, and the nicotine inhaler. Indeed, for FDA to decline to regulate Nicotine Water would be to create an immense regulatory void by permitting the inclusion of addictive and uncontrolled doses of nicotine in any food without FDA oversight.

Garret is not alone in developing alternative tobacco products of uncertain safety. Philip Morris Co. and other major tobacco companies are developing and beginning to market cigarettes that purportedly contain reduced amounts of cancer-causing agents. Many of these products are being, or are expected to be, marketed as safer than conventional tobacco products. The development of these nontraditional tobacco and nicotine products makes it essential that

FDA promptly define and articulate a consistent and scientifically rigorous approach to regulating such alleged “reduced-risk” products.

C. Conclusion

For the foregoing reasons, FDA should classify Nicotine Water as a “new drug” that cannot be marketed without FDA approval and invite Garret to submit a “new drug” application for the product. In the alternative, FDA should classify Nicotine Water as a food, and it should prohibit the marketing of Nicotine Water until Garret has filed a food additive petition with the Agency and the product has been approved according to normal agency standards and procedures.

D. Environmental Impact

This petition qualifies for categorical exclusion under 21 C.F.R. §§ 25.15, 25.30-25.32, and therefore does not require the preparation of an environmental assessment or an environmental impact statement. In any event, the action requested in this petition will not have any significant effect on the quality of the human environment.

In accordance with the requirements of 21 C.F.R. § 25.15, we assert we are not aware of any extraordinary circumstances.

Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

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Dated: December 18, 2001