IN THE FOOD AND DRUG ADMINISTRATION

Supplemental Petition for Regulation of QuickTest 5, Inc.'s NICOWater	)	Docket No. 01P-0573

Submitted on Behalf of the National Center for Tobacco-Free Kids, the American Academy of Pediatrics, the American Academy of Cancer Physicians, the American Cancer Society, the American College of Cardiology, the American College of Chest Physicians, the American Heart Association, the American Lung Association, the American Medical Association, the American Public Health Association, the American Society of Addiction Medicine, the American Society of Clinical Oncology, the American Thoracic Society, the Association of Asian Pacific Community Health Organizations, the Association of Maternal and Child Health Programs, the Association of Teachers of Preventive Medicine, the Community Anti-Drugs Coalitions of America, the Interreligious Coalition on Smoking or Health, the National Association of County and City Health Officials, the National Latino Council on Alcohol and Tobacco Prevention, the Oncology Nursing Society, and Oral Health America.

March 25, 2003

01P-0573

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SUPPLEMENTAL CITIZEN PETITION

The undersigned National Center for Tobacco-Free Kids, the American Academy of Pediatrics, the American Academy of Cancer Physicians, the American Cancer Society, the American College of Cardiology, the American College of Chest Physicians, the American Heart Association, the American Lung Association, the American Medical Association, the American Public Health Association, the American Society of Addiction Medicine, the American Society of Clinical Oncology, the American Thoracic Society, the Association of Asian Pacific Community Health Organizations, the Association of Maternal and Child Health Programs, the Association of Teachers of Preventive Medicine, the Community Anti-Drugs Coalitions of America, the Interreligious Coalition on Smoking or Health, the National Association of County and City Health Officials, the National Latino Council on Alcohol and Tobacco Prevention, the Oncology Nursing Society, and Oral Health America ("Petitioners") respectfully submit this Petition pursuant to 21 C.F.R. § 10.30 and section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a). This Petition follows up on, and is intended as a supplement to, the Citizen Petition filed by the National Center for Tobacco-Free Kids and others on December 18, 2001 and granted by the Food and Drug Administration ("FDA") on July 1, 2002 (Docket No. 01P-0573).

A. Action Requested

Petitioners request that FDA determine that NICOWater – a product containing bottled water and approximately four milligrams of nicotine – is not a homeopathic remedy under the FFDCA, and that the Agency reaffirm its previous determination that this product is an unapproved new drug that may not be marketed without prior FDA approval under FFDCA section 505(a).

NICOWater's manufacturer, QuickTest5 ("QT5"), is promoting its product as a homeopathic remedy for the reduction of nicotine cravings. This is a transparent, cynical, and baseless attempt to evade an earlier FDA determination that NICOWater is a drug that is subject to the Agency's premarket approval requirements. This is not the first time that manufacturers of NICOWater have attempted to evade FDA premarket review. QT5's predecessor company, S & F Garret ("Garret"), sought to market NICOWater as a dietary supplement in order to escape Agency premarket review. FDA unequivocally rejected this attempt and should do the same with respect to QT5's efforts to evade FDA review by marketing its product as a homeopathic remedy.

B. Statement of Grounds

1. Background

On December 18, 2001, the National Center for Tobacco-Free Kids, along with 17 other groups, submitted a Citizen Petition to FDA regarding a product called Nicotine Water, manufactured by Garret. This Petition, without the attachments, is Attachment A hereto. Nicotine Water contained bottled water and nicotine in an amount equivalent to two cigarettes. Garret sold Nicotine Water over the internet and claimed that it was a dietary supplement not

subject to the laws governing FDA's regulation of drug products. The December 2001 Citizen Petition asked FDA to determine (1) that Nicotine Water was not a dietary supplement and (2) that it was in fact a drug that could not be marketed without prior Agency approval. FDA agreed on both counts and granted the December 2001 Petition in July 2002. Letter from Dennis E. Baker, Associate Commissioner of Regulatory Affairs, Food and Drug Administration, to William B. Schultz *et al.*, July 1, 2002 ("Baker Letter") (Attachment B hereto).[1]

In April 2002, while the December 2001 Petition was pending before FDA, QT5 purchased the patent on Garret's product (Patent No. 6,268,386) and proceeded to change the name of the product from Nicotine Water to NICOWater.[2] The patent purchased by QT5 in April 2002 governs the current version of NICOWater.[3] Nicotine Water and NICOWater are *therefore the same product, governed by the same patent*, and FDA's July 2002 decision granting the December 2001 Petition applies fully to the product and company addressed in this Petition.[4] Even the promotional pitches for the old version of the product and the new version are virtually identical.[5] Thus, FDA has already held that NICOWater is a drug that may not be marketed

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[1] *See also* Press Release, "FDA Grants Citizen's Petition Seeking Unapproved Drug Classification for 'Nicotine Water'," July 2, 2002, *available at* http://www.fda.gov/bbs/topics/NEWS/2002/NEW00818.html (Attachment C hereto).

[2] *See* Letter from Matthew L. Myers, National Center for Tobacco Free Kids, to Lester Crawford, Jr., Deputy Commissioner, Food and Drug Administration, May 23, 2002 (supplementing Center's original Nicotine Water petition with updated information on product name and ownership and patent purchase) (Attachment D hereto).

[3] *See* Form 8-K of QT 5, Inc., filed with the Securities and Exchange Commission, January 24, 2003 (Attachment E hereto) at 3 (noting that QT5's "first nicotine beverage product" under Patent No. 6,268,386 "is anticipated to be" NICOWater).

[4] FDA's decision granting the December 2001 petition indicated that NICOWater might contain a different active ingredient than Nicotine Water (nicotine polacrilex, as opposed to nicotine), but went on to treat the products, even with that possible difference, as identical for purposes of its analysis. Attachment B at 2. As discussed below, at note 6, QT5 claims that its latest version of NICOWater contains a "nicotinum formula." Petitioners do not believe that this formula is different from the one used in previous versions of the product, but rather is just another effort by QT5 to recharacterize its product in an effort to avoid FDA jurisdiction. Nicotinum is simply another term for nicotine. *See* entry in Homeopathic Pharmacopoeia (December 2000 ed.) for "Nicotinum" ("HPUS Entry") (Attachment F hereto) (describing "nicotine" as the "name in contemporary use" for Nicotinum). Even assuming the formula is different, however, FDA should, consistent with its past ruling, disregard this difference and treat the most recent version of NICOWater in the same manner as versions of the product that the Agency has already deemed subject to premarket review.

[5] *Compare* Attachment D (Exhibit C) (*quoting* QT5's Steve Reder on May 22, 2002 to the effect that the company's product is for "when you want to smoke but can't or when you .. . want to

without the Agency's approval. Since the granting of the December 2001 Petition, however, QT5 appears to have determined that, while it cannot escape FDA approval requirements by labeling its product a dietary supplement, it *can* escape these requirements by labeling the product a "homeopathic" remedy for the treatment of nicotine withdrawal.[6] The "homeopathic" version of QT5's product contains "approximately 4mg of nicotine, and will be sold in 16.9 Fl. Oz. bottles."[7] According to news reports, QT5 plans to launch NICOWater during the second quarter of this year – *i.e.,* as soon as next month --, in spite of FDA's previous determination that the Agency must approve the product before marketing.[8]

FDA should reaffirm its previous holding that NICOWater is an unapproved new drug and reject QT5's efforts to "reinvent" its product in order to evade FDA regulation, for the following reasons.

2. Legal Grounds

Nicotine is recognized as a homeopathic substance.[9] QT5 appears to be under the impression, however, that the mere presence of nicotine in NICOWater makes that product a homeopathic remedy that is shielded from FDA review regardless of the purpose for which the product is being offered.

This is false. Most important, FDA has *already* determined that NICOWater is a drug subject to premarket Agency review. This determination is consistent with FDA's requirements for other nicotine products, such as Nicorette and Nicoderm CQ, that are intended to be used by those addicted to nicotine.[10] Some of these products are virtually identical in nicotine content to NICOWater. For example, the most potent version of Nicorette gum, which FDA has subjected

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smoke and shouldn't") *to* "QT 5, Inc. Merger Effective," January 9, 2003 ("Nicowater is . . . for 'when you want to smoke but can't or can smoke but shouldn't'") (Attachment G hereto), available at http://quickstart.clari.net/qs_se/webnews/wed/cp/Bca-qt-5.R9hD_DJ9.html.

[6] *See* "QT 5, Inc. Introduces NICOWater; 'The World's First Nicotine Beverage as an Alternative to Smoking'", *Business Wire*, March 3, 2003, (hereafter "NICOWater Announcement") (Attachment H hereto) (reporting that "NICOWater is a clear, colorless and odorless homeopathic nicotinum formula" and that it is designed to "relieve the symptoms of tobacco cravings"). QT5's most recent 8-K, filed with the SEC in January 2003, confirms that the company believes that "as the Company intends to label and market Nico Water, it is not a new drug under the act . . . ." *See* Attachment E at 4.

[7] NICOWater Announcement, *supra* n.6.

[8] *Id.*

[9] *See* HPUS Entry, *supra* n. 4.

[10] *See* Baker Letter at 2 (analogizing Nicotine Water to other FDA-approved products containing nicotine as the active ingredient).

to premarket review and approval, contains the same amount of nicotine per piece of gum as NICOWater contains per bottle – four milligrams.[11] For FDA to permit the marketing of NICOWater as a homeopathic remedy, without premarket review, would be an unwarranted and extreme departure from the Agency's precedents and would permit the manufacturers of equally potent nicotine products (including those already regulated by FDA) to argue that *their products too* are homeopathic remedies that should not be subject to premarket review. This is surely not an outcome FDA would endorse.

The fact that nicotine is recognized as a homeopathic substance should not disturb FDA's current approach to nicotine products like NICOWater or Nicorette. Homeopathic substances are classified and regulated *as drugs* under the FFDCA. 21 U.S.C. § 321(g)(1)(A) (defining "drug" to include "articles recognized in the . . . official Homeopathic Pharmacopoeia of the United States").[12] Thus, on its face, NICOWater, whether it contains a homeopathic substance or not, is subject to premarket review like any other drug.[13]

It is true that *as a matter of discretion*, FDA has chosen not to enforce the new drug approval requirements with respect to some homeopathic drugs.[14] The Agency has made clear, however, that its general regulatory requirements for drugs should be relaxed as to homeopathic products *only where the homeopathic drug is being used in a manner consistent with the recognized practices and theories of homeopathic medicine.* FDA's Compliance Policy Guide relating to homeopathic drugs could not be clearer:

> "[In determining the conditions under which homeopathic drugs may be marketed in the United States], [a]gency compliance personnel should particularly consider

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[11] *Compare* NICOWater Announcement (noting that one bottle contains "approximately 4 mg of nicotine") *to* Approved Labeling for Nicorette (Attachment I) (noting nicotine content of Nicorette).

[12] *See also Meserey v. United States*, 447 F. Supp. 548 (D. Nev. 1977) (holding that homeopathic products are drugs under the FFDCA).

[13] Moreover, as FDA previously recognized, NICOWater is intended for the treatment or mitigation of nicotine addiction and is intended to affect the structure and function of the human body. *See* Baker Letter at 3-5 (noting that patent information and promotional claims made for Nicotine Water render that product a drug under the FFDCA). Thus, NICOWater also satisfies the alternative definitions of "drug" under 21 U.S.C. § 321(g)(1)(B) and (C) and is therefore subject to regulation under those provisions, too.

[14] Joseph Page, "Federal Regulation of Tobacco Products and Products that Treat Tobacco Dependence: Are the Playing Fields Level?", 53 *Food & Drug L. J.* 11, 26 (1998) ("FDA's position on homeopathic medications appears to be that they are subject to all statutory requirements and regulations governing drugs, but that the agency will enforce the law selectively, in accordance with published guidelines spelling out the conditions under which homeopathic drugs may be marketed.")

whether a homeopathic drug is being offered for use (or promoted) significantly beyond recognized or customary practice of homeopathy. If so, priorities and procedures concerning the agency's policy on health fraud would apply."

FDA Compliance Policy Guide 7132.15 (hereafter "CPG") (Attachment J hereto), *available at* http://www/fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg400-400.html.

NICOWater is being offered for use in a manner that is completely inconsistent with the traditional practice of homeopathy. Indeed, the use of NICOWater to address nicotine addiction directly violates the two cardinal rules of homeopathy.

The first of these rules is the so-called "law of infinitesimals," which holds that statistically insignificant amounts of certain active ingredients, when heavily diluted, can serve a therapeutic purpose.[15] In conformance with this rule, homeopathic remedies feature barely measurable, or immeasurable, amounts of their active ingredients. In fact, it is the infinitesimal amount of the active ingredients in homeopathic drugs that has caused FDA to determine that they should be treated differently under the Agency's enforcement regime than other drugs.[16]

As noted, NICOWater contains approximately *four milligrams* of nicotine. This amount is clearly measurable and significant and raises safety issues not raised by traditional homeopathic remedies. Indeed, the very purpose of NICOWater, like the purpose of other nicotine products regulated as drugs by FDA, is to provide smokers with a pharmacologically significant amount of nicotine to satisfy their cravings for that substance. The proposed labeling for Nicorette gum makes clear that four milligrams of nicotine – the amount of nicotine found in NICOWater -- may be sufficient to cause sickness in adults as well as children.[17] This fact alone disqualifies NICOWater as a homeopathic remedy. Equally dispositive is the fact that NICOWater does not appear to meet the dilution requirements for over the counter homeopathic nicotine. The accepted level of dilution for over the counter ("OTC") homeopathic nicotine is

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[15] Isadora Stehlin, "Homeopathy: Real Medicine or Empty Promises" (FDA Consumer Magazine December 1996) (hereafter "Stehlin"), *available at* http://www.fda.gov/fdac/features/096_home.html (Attachment K hereto).

[16] As one FDA official has indicated, "the disparate treatment [of homeopathic drugs by FDA] has been primarily based on the uniqueness of homeopathic products, the lack of any real concern over their safety because they have *little or no pharmacologically active ingredients* . . . ." *Id.* (*quoting* FDA Official Edward Miracco) (emphasis added).

[17] Approved Labeling for Nicorette, *supra* n.11, at 37 ("**Keep out of reach of children and pets.** Pieces of nicotine gum may have enough nicotine to make children and pets sick.") (Bold in original); 47 (noting that use of Nicorette can cause "hiccups, heartburn and other stomach problems.").

one part per million ("6x"),[18] while the dilution level of the nicotine in NICOWater appears to be only approximately one part per hundred thousand ("5x"). If this is true, NICOWater may not be sold OTC (as appears to be QT5's intention).[19] More generally, the insufficient dilution level for nicotine in NICOWater further demonstrates that that product does not comply with accepted principles of homeopathic medicine and should be subjected to FDA premarket review like any other drug.

The second cardinal rule of homeopathy that NICOWater violates is the "law of similars," which holds that substances that in large doses cause certain diseases should be applied in small doses to cure these diseases.[20] For example, under this principle, nicotine could be used in small doses to cure nicotine *overdosing*. But it is entirely inconsistent with homeopathic principles to give a homeopathic substance to address *withdrawal symptoms related to that substance* – the homeopathic solution to this problem is to reduce further the amount of nicotine in one's system, not to increase it. Thus, the use of NICOWater for the purpose set forth by its manufacturer is 180 degrees removed from the traditional homeopathic solution to the problem of nicotine withdrawal.

In short, NICOWater is in no way entitled to the preferential treatment FDA affords to homeopathic drugs that are used consistent with traditional homeopathic principles. Indeed, QT5's attempt to evade FDA regulation by characterizing its product as a homeopathic remedy should not only be rejected; it also may amount to health fraud and certainly warrants further investigation by the Agency, consistent with FDA's announced enforcement regime for homeopathic products.[21]

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[18] HPUS Entry, *supra* n.4.

[19] *See* Stehlin, *supra* n.15, at p.3 (noting that principal regulatory problem faced by FDA regarding homeopathic remedies is the improper sale of prescription products OTC).

[20] *Id.* at pp. 1-2 (describing "law of similars").

[21] It is also unclear whether QT5 has complied with *any* of the labeling, registration, listing, and manufacturing requirements set forth in the FDA Compliance Policy Guide regarding homeopathic products. For instance, homeopathic drugs must be labeled in accordance with the labeling provisions of the FFDCA (sections 502 and 503 of the Act) and 21 C.F.R. § 201. Further, all firms which manufacture, prepare, propagate, compound, or otherwise process homeopathic drugs must register as drug establishments. 21 C.F.R. § 207. Homeopathic drug products must also be manufactured in conformance with good manufacturing practices. 21 C.F.R. § 211. *See generally* CPG 7132.15, *supra*, pp. 4-5. Given the casual way in which QT5 has attempted to reinvent its product, FDA should examine closely whether compliance with any of these statutory and regulatory requirements has taken place.

3. Conclusion and Request for Expeditious Ruling

Just as FDA rejected the claim that NICOWater is a dietary supplement, so too should it reject the claim that the product is a homeopathic remedy. The product is no different now from what it was in July 2002, when FDA determined that it was subject to premarket approval requirements. At best, the argument that NICOWater is immune from these requirements as a homeopathic remedy is baseless. At worst, it is fraudulent. In either case, FDA should grant this Petition and immediately notify QT5 that it may not market NICOWater without FDA approval

As noted above, press reports suggest that QT5 intends to market NICOWater as soon as next month. Petitioners therefore request that FDA adjudicate this Petition in an expedited manner and that it then proceed with all appropriate regulatory action against QT5 to prevent the marketing of NICOWater in the absence of FDA review.

C. Environmental Impact

The Petitioners claim a categorical exemption under 21 C.F.R. § 25.31.

D. Economic Impact

No economic information has been requested by the Commissioner. 21 C.F.R. § 10.30.

E. Certification

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

Respectfully submitted,

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ATTACHMENTS

Submitted on Behalf of the National Center for Tobacco-Free Kids, the American Academy of Pediatrics, the American Academy of Cancer Physicians, the American Cancer Society, the American College of Cardiology, the American College of Chest Physicians, the American Heart Association, the American Lung Association, the American Medical Association, the American Public Health Association, the American Society of Addiction Medicine, the American Society of Clinical Oncology, the American Thoracic Society, the Association of Asian Pacific Community Health Organizations, the Association of Maternal and Child Health Programs, the Association of Teachers of Preventive Medicine, the Community Anti-Drugs Coalitions of America, the Interreligious Coalition on Smoking or Health, the National Association of County and City Health Officials, the National Latino Council on Alcohol and Tobacco Prevention, the Oncology Nursing Society, and Oral Health America.

March 25, 2003

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By Messenger

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Re: Citizens Petition
Docket No. 01P-0573

Dear Sir or Madam:

Please find enclosed an original and 4 copies of the Supplemental Petition submitted on behalf of the National Center for Tobacco-Free Kids and others for Regulation of QuickTest 5, Inc.'s NICOWater product.

Please file-stamp one of the copies and return it with the messenger who has delivered these papers to you.

Thank you for your attention to this matter.

Sincerely,

Carlos T. Angulo

Carlos T. Angulo

Enclosures