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November 10, 2003

BY HAND AND U.S. MAIL

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

2003 NOV 10 14:40

Re: Regulation of NICOWater™ (Docket No. 01P-0573)

Dear Sir or Madam:

On behalf of GlaxoSmithKline Consumer Healthcare, LP (“GSK”), we are writing to provide the Food and Drug Administration (“FDA”) with recent information about the continuing efforts of QT5, Inc. (“QT5”) to sell its nicotine-containing beverage product, NICOWater™, as an over-the-counter homeopathic product in the United States. As GSK explained in its earlier submissions to the agency, NICOWater is being marketed by QT5 as an unapproved new drug in violation of Section 505(a) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 355(a) (“FDCA”). The information described briefly below demonstrates that, in the absence of enforcement action by FDA, QT5 has vigorously sought to expand distribution of this product throughout the United States.¹

Specifically, during the past few months, QT5 has arranged for retail sale of NICOWater through both the Eckerd and Rite Aid pharmacy chains. QT5 reports that NICOWater is available at all 2600 Eckerd locations in 21 states, and Rite Aid will be the first major retailer to offer NICOWater to the entire west coast as well as many mid-

¹ Another company is also seeking to make nicotine-containing fruit drinks “available as an alternative for people trying to stop smoking.” Platinum Products has acquired the rights to patent number 6,268,386, and is currently engaged in litigation with QT5 over the rights to market nicotine-containing beverage products. No matter which party prevails, it appears that there is substantial interest in marketing such products to aid in smoking cessation efforts. See Nicotine Fruit Juice, BeverageDaily.com, May 8, 2003 (Exhibit A).

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western markets not previously served.² In addition, QT5 has established agreements with five new regional distributors that will reportedly make NICOWater available through a variety of convenience and hospitality locations in Georgia, Alabama, Massachusetts, New Hampshire, and the Chicago metropolitan area.³

At the same time, QT5 has facilitated the ability of consumers to purchase NICOWater directly over the Internet. Indeed, QT5's website includes a link to another website (www.bevsource.com) where the product can be purchased on-line.⁴ Although QT5 has indicated that it would sell NICOWater only to individuals over the age of 18 and the product's packaging states that it should not be sold "from any source where proof of age cannot be verified," bevsource.com does not appear to have established any restrictions whatsoever to prevent on-line sales of NICOWater to minors. We recently ordered NICOWater from this site and, at no point in the process, were we asked to provide information about the age of the purchaser.

In its letters of March 21, 2003, and July 14, 2003, GSK demonstrated that NICOWater can not be sold as an OTC homeopathic product under the FDCA. That conclusion was endorsed by the Council on Pharmacy of the Homeopathic Pharmacopoeia Convention of the United States when it flatly rejected QT5's request to change the permissible potency for OTC nicotinum from 6X to 5X. Nevertheless, rather than reformulating its product to ensure consistency with these regulatory requirements, QT5 has embarked on an aggressive marketing campaign to expand distribution of this product. And, in connection with that campaign, QT5 is asserting that NICOWater "relieves the symptoms of tobacco cravings" – a claim that renders NICOWater an unapproved new drug product.

In fact, both the packaging and labeling for NICOWater contain the following description of the use of the product: "**INDICATIONS:** Relieves the symptoms of tobacco cravings."⁵ In addition, QT5's website describes NICOWater as a product that "has been developed for adult smokers who suffer from the symptoms of tobacco cravings. . . ."

² See Press Release, QT5, Inc., "NICOWater is Now Available at Eckerd Drug Store Chain," July 28, 2003 (Exhibit B); Press Release, QT5, Inc., "NICOWater Available in Rite Aid Stores Chainwide," November 3, 2003 (Exhibit C).

³ See Press Release, QT5, Inc., "QT5 Announces Signing of Five New Regional Distribution Partners," Oct. 1, 2003 (Exhibit D). QT5 also announced on November 3, 2003, that it had entered into a strategic partnership with Adirondack Pure Springs Mt. Water Company which would provide QT5 with "state-of-the-art bottling facilities" and additional sales and marketing expertise.

⁴ See www.qt5inc.com/About%20NicoWater.htm (Exhibit E).

⁵ See Exhibit F.

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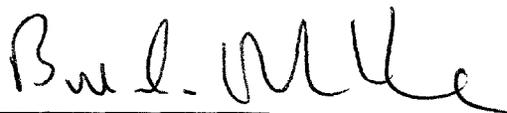
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Moreover, QT5 has sponsored a radio advertisement for NICOWater that declares the product “actually relieves the symptoms of tobacco cravings” and “can quench your tobacco cravings.”⁶ Accordingly, in light of these drug claims and the fact that QT5 is not in compliance with the requirements set forth in Section 400.400 of FDA’s Compliance Policy Guide,⁷ GSK again urges FDA to advise QT5 that it must immediately cease distribution and marketing of NICOWater in this manner.

Thank you for your attention to this request.

Sincerely,



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Enclosures: as stated

⁶ See e.g., Attached Transcript of Radio Advertisement posted on QT5’s website (Exhibit G).

⁷ See Food and Drug Administration, Compliance Policy Guide (CPG 7132.15), Section 400.400: Conditions Under Which Homeopathic Drugs May Be Marketed (Mar. 1995).