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July 14, 2003

BY HAND

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

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

Dear Sir or Madam:

On behalf of GlaxoSmithKline Consumer Healthcare, LP ("GSK"), we are writing to update the Food and Drug Administration ("FDA") on the latest developments concerning NICOWater™ -- a nicotine-containing beverage product that is marketed in the United States by QT5, Inc. ("QT5"). As described in more detail below, the Council on Pharmacy of the Homeopathic Pharmacopoeia Convention of the United States ("HPCUS") recently rejected QT5's request that the permissible over-the-counter ("OTC") potency for nicotinum be changed from 6X to 5X. Nevertheless, QT5 announced last week that it has commenced distribution of NICOWater as an OTC product and it does not appear that the product has been reformulated to be consistent with the Homeopathic Pharmacopeia of the United States ("HPUS").[1] Accordingly, in light of these developments, GSK once again urges FDA to advise QT5 that it cannot market NICOWater in this manner.

Specifically, in its March 21, 2003, submission on NICOWater, GSK set forth the bases for its conclusion that NICOWater cannot legally be marketed as an OTC homeopathic product. GSK pointed out that, based on QT5's description of NICOWater, each bottled product contains approximately four milligrams of nicotine in 16.9 fluid ounces of water.[2] That formulation translates to a concentration of 8 parts of nicotine per one million parts of water (i.e., 8 ppm) or approximately 1 part of nicotine per 100,000 parts of water. Under HPUS, nicotinum can only be marketed as an OTC product at a potency of 6X – that is, a dilution of 1/1,000,000 of the "mother tincture" containing nicotinum. We understand that, for liquid preparations containing nicotinum, the mother

[1] Shortly following QT5's announcement that product is being shipped in the United States, counsel for GSK requested counsel for QT5 to provide additional information about the potency level of NICOWater. Counsel for GSK has not received a response to that request.

[2] *See* Press Release, QT 5, Inc., QT 5, Inc. Introduces NICOWater; "The World's First Nicotine Beverage as an Alternative to Smoking" (Feb 27, 2003).

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tincture containing nicotinum is already diluted at a factor of 1/100. Thus, a homeopathic product containing a 6X potency for nicotinum actually contains one part of nicotine per 100,000,000 parts of water. Since NICOWater is being offered for sale at a concentration substantially greater than the permissible OTC potency, it cannot be sold as an OTC product.

In recognition of this problem, QT5 submitted a request to HPCUS on March 12, 2003, asking that the permissible OTC potency for nicotinum be changed from 6X to 5X.[3] In support of that request, QT5 asserted that the scientific literature supported this change and that orally ingested OTC products contain the same level of nicotine as a 5X nicotinum homeopathic product. QT5's request and supporting data were subsequently considered by the Council on Pharmacy of HPCUS during a special meeting on May 4, 2003. As can be seen from the enclosed report of the Council, QT5's request for a change in the permissible OTC potency level for nicotinum was carefully considered following a full presentation by QT5, including its outside legal counsel. And, following that presentation, the Council flatly rejected QT5's request for a proposed change in the nicotinum OTC potency by a vote of 15 to 1 with five abstentions.[4]

Notwithstanding this decision of the Council on Pharmacy of HPCUS, QT5 remains determined to market NICOWater as an OTC homeopathic product. Indeed, on May 28, 2003, the company announced its national launch and roll-out of NICOWater.[5] More recently, QT5 indicated that it had commenced shipments of NICOWater. In a July 8, 2003, press release, QT5's President declared that "[a]s we ramp up our production and broaden the scope of our NICOWater(TM) distribution networks, we continue to find a very high level of enthusiasm. We have already received some impressive opening orders from a number of national chain stores and look forward to announcing increased consumer availability in the near future."[6] The Vice President of Sales for QT5 further stated that "[t]he majority of shipments went to independent distributors and we are extremely pleased with the way NICOWater has been received by both the consumers and our resellers."[7]

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[3] *See* Letter from David Rosen, Counsel for QT5, Inc. to Clark Baker, Chairman of Editorial Committee, HPCUS, March 12, 2003. (Exhibit A)

[4] *See* Memorandum to Members of the Council of Pharmacy and HPCUS Board of Directors from J.P. Borneman, Regarding COP Meeting Report, May 4, 2003. (Exhibit B) It should be noted that the only voting member who agreed with QT5's proposed change disclosed that he serves as a consultant to QT5.

[5] *See* "QT5, Inc. Announces National Launch and Rollout of NICOWater: Multi-Million Dollar Development Program Culminates in Breakthrough Homeopathic Product," May 28, 2003. (Exhibit C)

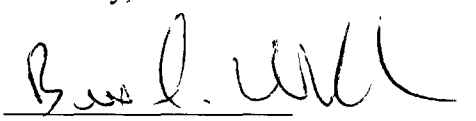
[6] *See* "QT5, Inc. Commences NICOWater Shipments," July 8, 2003. (Exhibit D)

[7] On May 30, 2003, QT5 also announced that NICOWater was being shipped to the Brooks Pharmacy chain, and to Northeast Beverage Corp., Rhode Island Distributing, Providence Beverage, and C&C Distributing for distribution to multiple northeastern states. *See* "Brooks Pharmacy Chain is First To Introduce NICOWater," May 30, 2003. (Exhibit E) Although Brooks subsequently halted distribution of the product in the wake of adverse publicity and public reaction, it does not appear that other distributors have done so as well. *See* "Distributor Halting Sale of Nicotine Water Targeted by Bill," June 6, 2003. (Exhibit F)

In light of the foregoing, FDA must take action to address unlawful distribution of NICOWater in the United States. As GSK explained in its earlier letter to the docket, a homeopathic medicine may be marketed in the United States without a new drug application in effect if the product complies with the relevant requirements contained in Section 400.400 of FDA's Compliance Policy Guide.[8] In this case, QT5 is plainly operating in a manner that is inconsistent with these requirements since NICOWater contains too great a concentration of nicotine to be marketed as an OTC product. In other cases involving homeopathic products, the agency has expressed especially strong concerns where manufacturers market prescription homeopathic products over-the-counter. Inasmuch as the same problem exists in the instant case, and the Council on Pharmacy of HPCUS has expressly indicated that NICOWater with a potency greater than 6X cannot be marketed as an OTC product, GSK urges FDA to advise QT5 that it must immediately cease distribution and marketing of NICOWater in this manner.

Thank you for your consideration of these comments.

Sincerely,



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adverse publicity and public reaction, it does not appear that other distributors have done so as well. *See* "Distributor Halting Sale of Nicotine Water Targeted by Bill," June 6, 2003. (Exhibit F)

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