

**HOMOEOPATHIC PHARMACOPOEIA CONVENTION
OF
THE UNITED STATES**

590 Richards Road
Wayne PA 19087

610 783 0987 Fax 610 783 5180 HPUS@aol.com www.hp.us.com

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket Nos. 01P-0572, 01P-0573, and 02P-0075

Dear Sir or Madam:

These comments are submitted by the Homoeopathic Pharmacopoeia Convention of the United States (“HPCUS”) in connection with certain statements made in various documents in the above-referenced dockets. The HPCUS publishes the Homoeopathic Pharmacopoeia of the United States, a document which has been published for over 100 years and which is recognized as an “official compendium” by Sections 501(b) and 502(e)(3) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 351(b) and 352(e)(3) (“FD&C Act”).¹

The above-referenced dockets all involve the marketing of a product consisting of water and nicotine and called NICOWater™. It was initially marketed as a dietary supplement. In July, 2002, the Food and Drug Administration (“FDA”) determined that NICOWater was not a dietary supplement, but, instead, an unapproved new drug marketed in violation of Section 505(a) of the FD&C Act. The manufacturer, QT5, Inc., is now marketing what appears to be the same product with the claim, on its web site, that “NICOWater™ is a **homeopathic formula** developed for adult smokers who suffer from the symptoms of tobacco cravings and find themselves in situations and/or environments where smoking is prohibited or discouraged.” (Emphasis added.)²

¹ In order to continually improve the HPUS, the HPCUS has begun to publish it on a rolling basis, rather than an entirely new edition at periodic intervals. This new service is called the Homoeopathic Pharmacopoeia Revision Service. For convenience, we refer to it as the “HPUS”.

² <http://www.nicowater.com/About%20NicoWater.htm> (accessed October 30, 2003).

While the HPCUS believes that it has developed, over the years, a mutually beneficial working relationship with FDA, the organization does not ordinarily take public positions on particular products. The facts of this matter, however, compel us to offer the following comments.

As has been noted by other commenters in these dockets, *see, e.g.*, the March 21, 2003 comments filed on behalf of GlaxoSmithKline Consumer Healthcare, LP, nicotine, under its Latin name, *nicotinum*, is the subject of an official monograph in the HPUS. As such, it is an appropriate drug for use in homeopathic medicine. Some of the petitioners cite the fact that NICOWater contains nicotine at a level which is equivalent to an allopathic dose. We believe that this point is not relevant. Sections 501(b) and 502(g) of the FD&C Act clearly contemplate that a drug can exist both as an allopathic or traditional product and as a homeopathic product.

The HPUS specifies the dilutions (drug concentrations) which, based on safety, it considers to be appropriate for use as over-the-counter (OTC) remedies. Drug concentrations above this level are considered prescription drugs.³ The official HPUS dilution level for OTC sale of *nicotinum* is 6X⁴.

In March, 2003, QT5 petitioned the HPCUS to revise the lowest permissible OTC potency for *Nicotinum* HPUS from 6X to 5X⁵. The members of the HPCUS Council on Pharmacy (“COP”) carefully reviewed the data presented by QT5 and permitted representatives of the company to make a presentation at the May 4, 2003 meeting of the COP. Based on the data presented by the company, as well as other recognized pharmacology sources consulted by the COP, the COP determined that there was an inadequate margin of safety, especially for children, if *Nicotinum* HPUS were available OTC at a dilution of 5X. The COP accordingly recommended to the Board of the HPCUS that the requested change not be made. (A copy of the minutes of that meeting are attached.) The Board adopted that recommendation in September, 2003.

FDA’s Compliance Policy Guide on homeopathy, CPG 7132.15 (400.400), provides, in part, that “[i]f the HPUS specifies a distinction between nonprescription (over-the-counter) and prescription status of products which is based on strength (e.g., 30x) – and which is more restrictive than Section 503(b) of the Act – the more stringent criteria will apply.”

It is our understanding that, notwithstanding the decision of the HPCUS, QT5 is currently marketing NICOWater as a claimed homeopathic OTC drug at the 5X dilution level. The

³ Drug concentrations and potencies are inverse, thus as the potency level goes up, the drug concentration decreases.

⁴ A homeopathic 6X is equivalent to a concentration of 0.001 mg/ml.

⁵ A homeopathic 5X is equivalent to a concentration of 0.01 mg/ml.

HPCUS strongly believes that this action amounts to a public affront not only to the HPCUS and its deliberative process, but also to the “official” status bestowed upon it by the FD&C Act. We accordingly call upon the FDA to take appropriate action promptly.

Respectfully submitted,

John A Borneman III, R.Ph.,
President,
Homoeopathic Pharmacopoeia Convention of the United States

Attachment: HPCUS Council on Pharmacy Minutes May 4 2003

⁶ Some of the petitioners cite the fact that NicoWater contains a drug at a level which is equivalent to an allopathic dose. We believe that this point is not relevant to the agency’s decision. Sections 501(b) and 502(g) of the FD&C Act clearly contemplate that a drug can exist both as an allopathic product and as a homeopathic product.