

VIA EMAIL AND FEDERAL EXPRESS

March 12, 2003

Homeopathic Pharmacopoeia Convention of the United States
Attn: Clark P. Baker, Chairman of Editorial Committee
4974 Quebec Street, N.W.
Washington, DC 20016

Re: Request for a Change in the OTC Potency Level of Nicotinum from 6X to 5X

Dear Mr. Baker:

I am writing to the Homeopathic Pharmacopoeia Convention of the United States ("HPCUS") on behalf of our client, QT5, Inc., to request a change in the over-the-counter ("OTC") potency level for Nicotinum from 6X to 5X. The current HPUS monograph for Nicotinum lists the OTC potency as 6X and it really should be 5X. This request is based upon both scientific and apparent homeopathic use evidence that Nicotinum at a 5X potency level is safe and effective for OTC use.

My client is proposing to bring to market a Nicotinum 5X liquid. The total amount of nicotine contained in the final product would be approximately 4 mg, based upon the company's manufacturing and packaging methods. This amount is no more than that contained in a single piece of nicotine-containing gum or lozenge product which are currently marketed for OTC sale.

I. The Scientific Literature Supports the Proposed Change

Attached for your review as Attachment A is a report from an independent pharmacologist/toxicologist (Dr. Sandra Morseth of Milestone Biomedical, Inc.) who reviewed the available literature and whose conclusion supports this request for potency change. As nicotine-containing gums and lozenges are already available on an OTC basis, the toxicologist focused on a number of issues: attractiveness of a nicotine containing liquid; reports from poison control centers on nicotine ingestion; and factors that influence absorption.

A review of the report indicates that that Dr. Morseth used the most conservative estimates in order to assess the worst case scenarios. Specifically, her analysis of safety is based on the theoretical accidental ingestion by a 25 kg child of 4 milligrams of nicotine diluted in 500 ml of liquid. As an initial matter, Dr. Morseth points out that the ingestion of the full 500 ml of

liquid by a young child is unlikely. However, assuming the ingestion of such an amount, her analysis indicates that, at worst, some children would experience acute low-level toxicity from which recovery would be expected in a few hours. Dr. Morseth states that the signs and symptoms of acute low level toxicity would be neither serious or life threatening, noting that there have been reports on children exposed to much higher nicotine doses who were either asymptomatic or suffered only mild effects from the exposure. As a result, Dr. Morseth's safety report supports QT5's request that the HPUS Nicotinum monograph be revised to allow a 5X potency for OTC Nicotinum products.

II. FDA Has Approved the Sale of Orally Ingested OTC Allopathic Drugs That Contain the Same Level of Nicotine as a 5X Nicotinum Homeopathic Product

Dr. Morseth's report further concluded that accidental exposure to 4 milligrams of nicotine in a 500 ml liquid form would be no greater than the risks associated with other currently marketed OTC nicotine products such as gums. As the HPCUS knows, the Food and Drug Administration ("FDA") has approved a number of OTC smoking cessation drug products in gum and lozenge form that contain anywhere from 2 to 4 milligrams of nicotine per dosage unit. We attach product labeling for several allopathic smoking cessation gum products as Attachment B. It is clear that FDA believes that the ingestion of 2 to 4 milligrams of nicotine an hour is safe when used according to the labeled instructions.

Based on FDA's conclusions as to allopathic nicotine-containing gum products, a homeopathic Nicotinum 5X product labeled in accord with FDA's Compliance Policy Guide 7132.15 would have a safety record equivalent to the FDA-approved nicotine products. For the HPCUS' information, QT5 intends to include in the labeling language such as the following: "Not for sale for those under 18. Proof of age required. Not for sale in vending machines or any source where proof of age can not be verified." This labeling language will further minimize any accidental risk of ingestion by children and infants by restricting the availability of the product.

III. Nicotinum at the 4X Strength Appears to be Available for OTC Use Outside of the United States

Finally, we understand from our European colleagues that Nicotinum at the 4X strength is allowable for OTC sale in both France and Germany. Attachment C contains relevant pages from the 1995 edition of a German publication, *Homoopathische Arzneimittel*, which references the use of Nicotinum at the 4D strength. It is our understanding that 4D and 4X represent the same strength. It is our further understanding that *Homoopathische Arzneimittel* is an industry publication that contains information on nonprescription drugs.

After you and your committee have reviewed this information, Both QT5 and I are sure that the HPCUS will feel confident that a 5X OTC potency level provides adequate safety protection for the public.

On behalf of my client, I want to thank you for your consideration of this request. If you have any questions, need any additional information or want to further discuss this matter, please contact me at (202) 756-8075.

Sincerely yours,

David L. Rosen, R.Ph., J.D.

cc: John A. Borneman, III, President
590 Richards Road
Wayne, Pennsylvania 19087

Eric L. Foxman, Chairman of HPCUS PRC
3741 Mitford Lane
Clinton, WA 98236

Mr. Steven Reder
President
QT5, Inc.