

**GRAYCARY**

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December 19, 2003

**VIA FEDERAL EXPRESS**

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


Re: Notice of QT5, Inc.'s Intent to File Comments  
Concerning Comments to Citizen Petition Docket No. 01P-0572  
and Supplemental Citizen Petition Docket No. 01P-0573

Dear Sir/Madam:

I am writing on behalf of our client QT5, Inc. with respect to the above-referenced Citizen Petition, Supplemental Citizen Petition, and recent comments submitted to this docket. In conjunction with the company, outside homeopathic pharmaceutical experts, and counsel, we have evaluated these recent comments concerning QT5, Inc.'s nicotine-containing beverage product, NICOWater™ and are in the process of preparing additional substantive comments for submission to the docket. These formal comments will demonstrate our continued position that the Citizen Petition and Supplemental Citizen Petition are without merit and should therefore be denied. Accordingly, we trust that the Agency will not take any action or issue a response to the Petitioners until such comments are received.

We will submit these substantive comments within the next 30 days.

Sincerely yours,



David L. Rosen, R.Ph., J.D.  
Counsel for QT5, Inc.

cc: QT5, Inc.  
Mr. Steve Reder

Michael Landa, Esq.  
FDA, Office of the Chief Counsel

**01P-0572**

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