

# Lil' Drug Store Products



**DATE:** June 17, 2004

**FROM:** Chris DeWolf  
President & Chief Executive Officer  
Lil' Drug Store Products, Inc.  
1201 Continental Place NE  
Cedar Rapids, IA 52402

**TO:** Dockets Management Branch (HFD-560)  
Attn: Cazemiro R. Martin or Gerald M. Rachanow  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5630 Fishers Lane,  
Rockville, MD 20857

**CC:** Charles J. Ganley, M.D. , FDA

**SUBJECT:** Vaporizer in a Bottle Clinical Studies

I am submitting this letter to inform the appropriate parties at the FDA that we will not be conducting the requested clinical studies for our Vaporizer in a Bottle product to be considered for inclusion in the final OTC Cough-Cold Monograph. We found that we could not complete the research studies in a format consistent with FDA requirements, at a price that justified the investment of capital into the brand with an uncertain study outcome.

I would like to personally thank everyone at the FDA that invested their time to meet with our team and educate and provide us with a possible solution and path to address our brand's future. I want to express our continued desire to work together with your team if any future issues should arise.

Regards,

Chris DeWolf  
President & CEO  
Lil' Drug Store Products, Inc.

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