

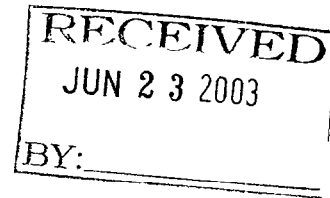
# Lil' Drug Store Products



**DATE:** June 19, 2003

**FROM:** James M. Nikrant  
Chief Executive Officer  
Lil' Drug Store Products, Inc.  
1201 Continental Place NE  
Cedar Rapids, IA 52402

**TO:** Elaine Abraham  
Division of OTC Drug Products (HFD-560)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
9201 Corporate Boulevard  
Bldg 2, Room S251  
Rockville, MD 20850



**RE:** Formal meeting request regarding Vaporizer in a Bottle® study guidance

This letter has been submitted in response to the FDA's ruling on the Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-The-Counter Human Use; Final Monograph for Combination Drug Products (Docket# 76N-052G). We are committed to conducting a study that would amend the combination cold, cough monograph to include Vaporizer in a Bottle into the final monograph as an antitussive.

The purpose of the meeting is to receive agency guidance on the proposal submitted 6/6/03. Our proposal provides two potential study options: a) an equivalence study and b) a clinical study. We would like to receive feedback on the methodology and appropriateness of the studies proposed before undertaking them. Once we have received your guidance, we will perform the study or studies, we will compile and present the results as evidence of the appropriateness of monograph inclusion.

Our proposed agenda includes:

- a) Discussion regarding in vitro study appropriateness and methodology (10 minutes)
- b) Discussion regarding clinical study appropriateness and methodology (20 minutes)
- c) Discussion regarding mobility/proximity issue (10 minutes)
- d) Discussion of combination versus single ingredient formulation (10 minutes)
- e) Guidance on statistical significance level required to demonstrate effectiveness (5 minutes)

Copies of the proposal were sent to Dr. Ganley (1 copy) as well as the Dockets Management Branch (3 copies). Per a conversation on 6/17/03 with Elaine Abraham we will also be including fifteen additional proposal copies to her attention, enclosed with this submission.

76N-052G

LET/2/

# Lil' Drug Store Products



Attendees representing Lil' Drug Store would include:

- James M. Nikrant - CEO, (LDS)
- Lorin Reicks - Operations & Regulatory Manager, (LDS)
- Chris DeWolf - President, (LDS)
- John Warner - Regulatory Consultant, (Independent Consultant)

We would prefer the list of FDA attendees to include:

- Cazemiro R. Martin
- Charles J. Ganley, M.D.
- Gerald M. Rachanow
- Elaine Abraham

Please respond back with a date and time available to meet regarding our proposal. Thank you.

Regards,

A handwritten signature in black ink, appearing to read "James M. Nikrant", with a long horizontal flourish extending to the right.

James M. Nikrant  
CEO  
Lil' Drug Store Products, Inc.

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

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DATE: JUN 23 2003

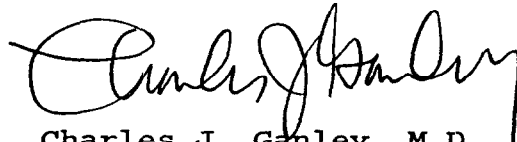
FROM: Director  
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 76N-0526

TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. \_\_\_\_\_

  
Charles J. Ganley, M.D.

Attachment