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 conversion on 6/17/03 with Elaine Abraham we will also be including fifteen additional proposal copies to her attention, enclosed with this submission.

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76N-052G

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Lil' Drug Store Products

Attendees representing Lil' Drug Store would include:

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

We would prefer the list of FDA attendees to include:

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

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

Regards,

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

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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

DATE: JUN 23 2003

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

SUBJECT: Material for Docket No. 76N-0536J

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