Lil' Drug Store Products

DATE: July 16, 2003

FROM: Lorin Reicks
Operations and Regulatory Manager
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: Specific meeting questions regarding the Vaporizer in a Bottle® study proposal

Per our phone conversation I have included a list of specific questions to be answered during our September 11th meeting on Vaporizer in a Bottle. 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.

The questions associated with the agenda items include the following:

1) Would successful completion of the in vitro test, as proposed, support monograph status for VIAB?
2) Are there any modifications of the in vitro test procedure the FDA would recommend?
3) Would successful completion of the in-vitro test support monograph status for a product with only a single active (i.e., camphor or menthol) or with the combination of the two?
4) Would successful completion of the clinical trial, as proposed, support monograph status for VIAB?
5) Are there any modifications of the clinical test procedure the FDA would recommend?
6) Would successful completion of the clinical trial support monograph status for a product with only a single active (i.e., camphor or menthol) or with the combination of the two?

Regards,

Lorin Reicks
Operations and Regulatory Manager
Lil' Drug Store Products, Inc.

76N-052G

LET 122

Lil' Drug Store Products | 1201 Continental Place NE | Cedar Rapids, IA 52402
Phone. 319-393-0454 | Fax. 319-393-3494 | Internet: www lildrugstore com | E-mail sales@lildrugstore com