MEMORANDUM OF TELECON

DATE: 11/06/07, 11:00 A.M.

APPLICATION NUMBER: NDA 22-129
DRUG PRODUCT: Lice Asphyxiator, 5% (b) (4)

BETWEEN:

Name: Mike Precopio, President, Summers Laboratories, Inc.
John Colyar, Vice President, Summers Laboratories, Inc.
Robert Bard, Vice President, Regulatory Affairs, Sciele Pharma, Inc.
Glen Park, Senior Director, Target Health, Inc.

Representing:

AND

Name: Division of Dermatology and Dental Products

Jill Lindstrom, M.D., Clinical Team Leader, Dermatology
Gordana Diglisic, M.D., Clinical Reviewer
Shulin Ding, Ph.D., PAL, OPS, ONDQA
Tarun Mehta, Ph.D., Chemist, OPS, ONDQA
Mat Soukup, Ph.D., Statistical Reviewer
Melinda Bauerlien, M.S., Regulatory Project Manager

SUBJECT: NDA 22-129

The teleconference was requested by the sponsor to discuss issues regarding the container/closure system for the product. An Information Request (IR) was sent on November 6, 2007 detailing information that the Agency needs to receive for the application.

1. The IR listed the areas in which there are differences in the study reports. The sponsor will need to provide corrected efficacy and safety summaries and study reports for each study as well as amended ISS and ISE.

   The sponsor stated that they will go back and revise the study reports and resubmit.

2. The proposed package design for the sponsor's product presents a risk for medication errors such as accidental ingestion. Submit a revised container closure system that can be readily distinguished from oral liquid products and is more in line with medicated

hair/scalp treatments products. Examples of such container/closure systems are push/open closure, bottle with nozzle/screw cap, push cap with squirt hole, etc.

The sponsor responded that they understand the concerns. They have not tested the viscosity to see if the product can go through the proposed caps.

The Agency responded that the sponsor needs to distinguish their product from oral packaging to prevent medication errors. The sponsor should look at the manufacturing and choose a viable closure. They must provide complete CMC information for the revised container/closure system and must qualify any new packaging components.

3. We also remind you of your commitment to provide the final study report for the in vivo bioavailablity study (#SU-01-2007) by October 31, 2007.

The sponsor stated that they will submit the final study report by the end of November. The data analysis is complete and there are no signs of absorption.

The sponsor stated that they should be able to provide a response within a month. The conversation ended amicably.

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/s/

Melinda Bauerlien
5/1/2008 02:04:38 PM
CSO

Jill Lindstrom
5/1/2008 02:43:59 PM
MEDICAL OFFICER