

MEMORANDUM OF TELECON

DATE: 1/16/08, 1:00 P.M.

APPLICATION NUMBER: NDA 22-129

DRUG PRODUCT: Lice Asphyxiator, 5% (b) (4)

BETWEEN:

Name: Mike Precopio, President, Summers Laboratories
John Colyar, Vice President, Summers Laboratories
Jules T. Mitchel, MBA, Ph.D., President, Target Health Inc.
Larry Dillaha, M.D. EVP and Chief Medical Officer, Sciele
Pharmaceuticals
Dan Tokich, Director Supplier Management, Sciele Pharmaceuticals
Stephanie Cooke, RAC, Director Regulatory, Sciele Pharmaceuticals

Representing: Summers Laboratories

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
Melinda Bauerlien, M.S., Regulatory Project Manager

SUBJECT: NDA 22-129

The teleconference was requested by the sponsor to discuss issues regarding comment 18 in the Agency's Information Request letter dated November 5, 2007.

Comment #18

The proposed package design for your 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.

Background:

In response to comment #18, Summers Laboratories (Summers) submitted a list of possible container closure modifications with the meeting request for their December 10 FDA teleconference. Comment #18 was briefly discussed with the Agency in the December 10, 2007,

meeting; however, as clinical issues were more pressing and the allotted meeting time was short, the discussion related to comment #18 was abbreviated. During the ensuing interval, Summers has further investigated available cap modifications. Summers proposes the following modification to the Lice Asphyxiator (benzyl alcohol), 5% (b) (4) container closure system to provide an acceptable container closure system more in-line with medicated hair/scalp treatment products that is readily distinguishable from oral liquid products.

Sponsor's Proposal:

Summers proposes to package the Lice Asphyxiator product in the current container closure system (polypropylene bottle (b) (4) listed in the NDA application) and to attach a (b) (4) (b) (4) (b) (4) (b) (4) would be applied by the pharmacist at the time of distribution of the product to the patient.

(b) (4) provides a revised container closure system more in-line with medicated hair/scalp treatment products and will readily distinguish the product from an oral liquid product. The application of a (b) (4) by the pharmacist has been an acceptable practice for other pharmacy dispensed products (example Capex shampoo). The pharmacist would be instructed to replace the existing cap (b) (4) via printed instructions included with the product. The sponsor would also provide a field notification and investigate and encourage that (b) (4) requirement be included in the directives to pharmacist banner read by the pharmacist prior to dispensing (e.g. First Data Bank or Gold Standard).

In that a source for an orifice reducing cap (b) (4) on which container closure stability has been demonstrated has not been located, Summers proposes to perform an accelerated and controlled room temperature condition stability program with the proposed (b) (4) (b) (4) and the existing bottle. The exposure time between the product and the dispensing cap will be limited to two weeks because the contents of the bottle will be used within two weeks of dispensing.

1. The Agency stated that the material in the (b) (4) is a different material and the sponsor will need to do additional qualifying studies such as the benzyl alcohol uptake test. The sponsor will also need to conduct a stability study at room temperature in the inverted position. The Agency stated that whichever option the sponsor chooses they will have to conduct the uptake, USP 661 and some accelerated stability studies. The sponsor can run the plan by the Agency.
2. The Agency stated that with the 8 oz bottle there is no easy way to measure 4oz. With the new closure, the patients will not be able to look through the cap to see the amount. The sponsor needs to address how the patient will measure the amount to be used.

The sponsor responded that the goal is to completely saturate the hair. The 4 oz is used as a rough estimate.

3. The Agency asked how the sponsor will ensure the (b) (4) placed onto the bottle.

The sponsor stated that they will send communications to the pharmacies regarding the cap as well as putting it into the databases in the pharmacies.

4. The Agency stated that the sponsor needs to provide dates for the submission of the following as soon as possible:
 - a. In-use uptake study for either choice
 - b. USP <661> for either choice
 - c. Stress stability test for the orifice reducer

The conversation ended amicably.

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this page is the manifestation of the electronic signature.**

/s/

Melinda Bauerlien
5/1/2008 02:05:48 PM
CSO

Jill Lindstrom
5/1/2008 02:27:23 PM
MEDICAL OFFICER