

PEDIATRIC (PARTIAL) WAIVER REQUEST

(b) (4) **(BENZYL ALCOHOL) 5% LOTION**
FOR THE
TREATMENT OF HEAD LICE
IND# 50,076
NDA# 22,129

Prepared by

TARGET HEALTH INC.
261 Madison Avenue, 24th Floor
New York, NY 10016

Submitted For

Summers Laboratories, Inc.
103 G.P. Clement Dr.
Collegeville, PA 19426

Submitted To

Susan Walker, MD
Division of Dermatologic and Dental Products
Food and Drug Administration
5901- B Ammendale Road
Beltsville, MD 20705-1266

Date October 12, 2007

Confidentiality Statement

The confidential information in this document is provided for review by you and your staff. Your acceptance of this document constitutes agreement that you will not disclose the information contained herein to others without written authorization from the Sponsor, Summers Laboratories, Inc.

1. PRODUCT NAME

The active ingredient in (b) (4) (benzyl alcohol), 5% Lotion is benzyl alcohol.

2. PROPOSED INDICATION

The proposed indication is for the treatment of head lice.

3. PEDIATRIC AGE GROUPS INCLUDED IN THE WAIVER REQUEST

Infants aged 0 to 6 months.

4. STATUTORY REASONS FOR WAIVING THE AGE GROUP

The studies necessary for this age group are impossible or highly impractical because the number of patients in the age group 0 to 6 months is so small (section 505B(a)(4)(B)(i) of the Act).

5. EVIDENCE THAT THE REQUEST MEETS THE STATUTORY REASONS

Epidemiological studies of head lice infestations have focused on school aged children. There are no reports in the literature of head lice occurring in children less than 6 months of age ⁽¹⁻⁴⁾. A head lice expert, conducting lice research for over 25 years, reports never having seen a child less than 6 months of age with head lice (T. L. Meinking, personal communication). The reason for this observation may be that infants have smaller diameter hair (approximately 30 μm) compared to older children and adults (70 μm) are not thick enough to enable female lice gonapods to grasp and lay eggs ⁽⁵⁾. In addition, infants, in contrast to pre-school and school aged children, may have a lower risk of infestation due to less social contact with infested individuals.

6. APPLICANT CERTIFICATION

Summers Laboratories, Inc. certifies that the above statements are correct to the best of their knowledge.



Michael J. Precopio
President, Summers Laboratories, Inc.

October 9, 2007
Date

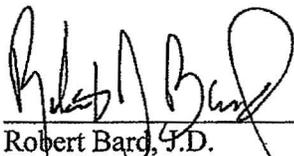
7. REFERENCES:

1. Meinking TL. Head Lice. In Resh VH, Cardé RT, Eds. Encyclopedia of Insects. San Diego, CA: Academic Press; 2003:664-6.
2. Meinking TL, Taplin D. Chapter 27: Infestations. In Schachner LA, Hansen RC, Eds. Pediatric Dermatology. Mosby; 2003.
3. Meinking TL, Burkhart , Elgart G. Chapter 83. In Dermatology. 2nd edition. Elsevier Publishers. In Press.
4. Meinking TL. In Current Problems in Dermatology. Mosby 1999;11:73-120.
5. Robbins CR. Chemical and Physical Behaviour of Human Hair. 4th Edition. Springer. 2002.

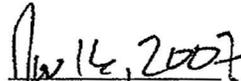


Debarment Certification

Sciële Pharma, Inc. hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug and Cosmetic Act in connection with NDA 22-129, Lice Asphyxiator (benzyl alcohol), 5% (b) (4)



Robert Barg, J.D.
Vice President of Regulatory Affairs



Date



103 G.P. Clement Drive
Collegeville, PA 19426
(610) 454-1471
FAX (610) 454-1475

customer service:
1-800-533-SKIN
info@sumlab.com

Debarment Certification

Summers Laboratories Inc. hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug and Cosmetic Act in connection with this application.

A handwritten signature in black ink, appearing to read "Mike Precopio", is written over a horizontal line.

Mike Precopio
President, Summers Laboratories

13 FEB 2007
Date

MEMORANDUM

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

CLINICAL INSPECTION SUMMARY

DATE: May 22, 2008

TO: Margo Owens, Regulatory Project Manager
Gordana Diglisic, M.D., Medical Officer
Division of Dermatologic and Dental Drug Products

FROM: Roy Blay, Ph.D.
Good Clinical Practice Branch I
Division of Scientific Investigations

THROUGH: Constance Lewin, M.D., M.P.H.
Branch Chief, Good Clinical Practice Branch I
Division of Scientific Investigations

SUBJECT: Evaluation of Clinical Inspections

NDA: 22-129

APPLICANT: Summers Laboratories, Inc.

DRUG: Lice Asphyxiator, (benzyl alcohol), 5% (b) (4)

NME: Yes

**THERAPEUTIC
CLASSIFICATION:** Standard

INDICATION: Treatment of head lice

**CONSULTATION
REQUEST DATE:** November 6, 2007

**DIVISION ACTION
GOAL DATE:** May 23, 2008

PDUFA DATE: July 15, 2008

I. BACKGROUND:

Lice Asphyxiator, (benzyl alcohol), 5% (b) (4) is indicated for the treatment of infection with pediculus humanus capitis (head lice) of the scalp hair.

The protocols inspected included #s SU-01-2005 and SU-02-2005, both entitled “A Multi-center, Randomized, Vehicle Controlled, Double Blind Clinical Trial to Evaluate the Efficacy and Safety of Summers Non-Pesticide Lice Asphyxiator (L.A.) for the Treatment of Head Lice”.

The object was to evaluate the safety and efficacy of home-use of two ten minute treatments of 5% lice asphyxiator (L.A.) of one week apart compared to a vehicle control. The main outcome measure was pediculocidal activity as determined by the presence of live lice two weeks after final treatment.

Site 1 was selected because all household members were enrolled at the same time. Site 2 was selected because the site had almost 100% efficacy for the active group and 0% efficacy for the vehicle group. Site 6 was selected because there was no difference in efficacy between the vehicle and active groups. Site 12 was selected because the site had unusually high efficacy for the vehicle group.

II. RESULTS (by Site):

Name of CI, IRB, or Sponsor City, State, or Country	Protocol #:/ Site #:/ # of Subjects:/	Inspection Dates	Final Classification
Terri Meinking and Heather Woolery Lloyd, M.D. Global Health Associates of Miami, 7800 S.W. 57th Avenue, Suite 219E South Miami, FL 33143	SU-01-2005/ Site 1/ 13	4-6 Feb 2008	NAI
Anne Lucky, M.D. Dermatology Research Associates, 7691 Five Mile Road, Suite 312, Cincinnati, OH 45230	SU-01-2005/ Site 2/ 8	13-20 Feb 2008	NAI
Anton Duke, M.D. Arkansas Pediatric Clinic 500 S. University, Suite 200, Little Rock, AR 72205	SU-02-2005/ Site 6/ 15	11-14 Feb 2008	VAI
Barry Collins, M.D. Advanced Clinical Research, LLC, 2107 Martin St. South, Suite 103, Pell City, AL 35128	SU-02-2005/ Site 12/ 15	28-29 Jan 2008	NAI
Summers Laboratories, Inc. 103 G.P. Clement Drive Collegeville, PA 19426-2044	Sponsor	8-11 Feb 2008	NAI
Target Health 261 Madison Avenue, 24 th Floor New York, NY 10016	CRO	19-22 May 2008	Pending (preliminary- NAI)

Key to Classifications

NAI = No deviation from regulations.

VAI-No Response Requested= Deviations(s) from regulations.

VAI-R = Response Requested = Deviation(s) from regulations.

OAI = Significant deviations from regulations.

Pending = Preliminary classification based on information in 483 and/or communications with the field; EIR has not been received from the field and complete review of EIR is pending.

1. Terri Meinking and

Heather Woolery Lloyd, M.D.

Global Health Associates of Miami,

7800 S.W. 57th Avenue, Suite 219E

South Miami, FL 33143

a. What was inspected: 26 families were randomized to the study, and records inspected included, but were not limited to, 100% of signed consent forms, source documents, drug accountability records, IRB approvals and correspondence and sponsor-generated correspondence.

b. General observations/commentary: Review of the records noted above revealed no significant discrepancies/regulatory violations.

c. Assessment of data integrity: Data appear acceptable in support of the respective application.

2. Anne Lucky, M.D.

Dermatology Research Associates,

7691 Five Mile Road, Suite

312 Cincinnati, OH 45230

a. What was inspected: The records of 87 subjects screened for this study were noted to be present and the consent forms for all 87 subjects were reviewed. 47 subjects were screen failures and 40 subjects were enrolled. Data on Case Report Forms (CRFs) for 10 subjects were compared to the source documents. Clinical notes and patient histories were reviewed. A sampling of CRFs rendered into PDF format and provided to the site by the sponsor was compared with the records residing in the site's computer system.

b. General observations/commentary: Review of the records noted above revealed no significant discrepancies/regulatory violations.

c. Assessment of data integrity: Data appear acceptable in support of the respective application.

3. Anton Duke, M.D.

Arkansas Pediatric Clinic
500 S. University, Suite 200,
Little Rock, AR 72205

- a. **What was inspected:** 70 subjects were screened and enrolled, and the records of all 70 subjects were audited.
- b. **General observations/commentary:** Inspection revealed two instances of inadequate source documentation regarding the designation of subjects as primary cohorts and a delay in a treatment visit for one family.
- c. **Assessment of data integrity:** The minor observations noted above are unlikely to have any significant effect on data integrity. Data appear acceptable in support of the respective application.

4. Barry Collins, M.D.

Advanced Clinical Research, LLC,
2107 Martin St. South, Suite 103
Pell City, AL 35128

- a. **What was inspected:** Consent forms for all 42 randomized subjects were reviewed. 39 subjects completed the study. The records for all randomized Primary Cohort Subjects and their household members were reviewed. Source data were compared to study listings for primary cohort members with respect to primary efficacy endpoints, adverse events, randomization, discontinuations, concomitant therapies, and drug reconciliation.
- b. **General observations/commentary:** Review of the records noted above revealed no significant discrepancies/regulatory violations.
- c. **Assessment of data integrity:** Data appear acceptable in support of the respective application.

5. Summers Laboratories, Inc.

103 G.P. Clement Drive
Collegeville, PA 19426-2044

- a. **What was inspected:** The study activities of the sponsor, Summers Laboratories, Inc. and their contractual agreements with the CROs that conducted the majority of the study activities were inspected. The trial master files of four of the study sites (#s 01, 02, 06, and 012) were reviewed, including IRB approvals, completed FDA 1572s, investigator CV's, and drug reconciliation records.
- b. **General observations/commentary:** Review of the records noted above revealed no significant discrepancies/regulatory violations.

- c. **Assessment of data integrity:** Data appear acceptable in support of the respective application.

6. Target Health

Note that this inspection will be concluded on May 22 or 23, 2008. A preliminary telephone communication (May 22, 2008) with (b) (4), Inspector, (b) (4), indicated that there were no significant findings to date and that a Form FDA 483 would not be issued.

- a. **What was inspected:**
- b. **General observations/commentary:**
- c. **Assessment of data integrity:**

IV. OVERALL ASSESSMENT OF FINDINGS AND RECOMMENDATIONS

Overall, the data generated by the sites of Mrs. Meinking/Dr. Woolery-Lloyd, Lucky, Duke, and Collins, appear acceptable in support of the pending application. Inspection of the sponsor, Summers Laboratories, Inc., revealed no objectionable observations. The inspection of the contract research organization used by Summers, Target Health, is almost completed as noted above and there have been no significant observations to date. The review division will be notified immediately if this inspection reveals any observations of significance.

{See appended electronic signature page}

Roy Blay, Ph.D.
GCP Reviewer
Good Clinical Practice Branch I
Division of Scientific Investigations

CONCURRENCE:

{See appended electronic signature page}

Constance Lewin, M.D., M.P.H.
Branch Chief, Good Clinical Practice Branch I
Division of Scientific Investigations
Office of Compliance

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/s/

Roy Blay
5/22/2008 02:45:05 PM
CSO

Constance Lewin
5/23/2008 07:44:07 AM
MEDICAL OFFICER



**Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation ODEIII**

FACSIMILE TRANSMITTAL SHEET

DATE: September 17, 2007

To: Glen Park, Pharm.D.

From: Victoria Lutwak for Melinda Bauerlien

Company: Target Health Inc. /Summers
Laboratories, Inc.

Division of Dermatology and Dental Products

Fax number: (212) 681-2105

Fax number: (301) 796-9894/9895

Phone number: 212-681-2100

Phone number: (301) 796-2110

Subject: NDA 22-129 (b) (4)

Total no. of pages including cover: 4

Comments: Please see the attachment.

Document to be mailed: YES NO

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Attachments

NDA 22-129

Lice Asphyxiator (benzyl alcohol), (b) (4) 5%

Information Request

Please refer to your New Drug Application (NDA) submitted June 15, 2007 under sections 505(b)(1) of the Federal Food, Drug and Cosmetic Act for (b) (4)

The medical office has the following request for information:

Please clarify data discrepancies between Clinical Study Report and Data listing for SU-01-2005 and SU-02-2005, Analysis of Adverse Events and ISS, and New Number of Subjects Exposed to L.A.5% (SU-03-2005).

1. Study SU-01-2005

Disposition of subjects:

- *Clinical Study Report:*

Table 1.1.1:

5% L.A. – reason for premature termination:

Investigators’ clinical decision: 1 (primary cohort)

Other: 5 (primary cohort)

Deviate from the protocol: 2

Vehicle - reason for premature termination:

Treatment failure: 51

Table 1.1.2:

5% L.A. – reason for premature termination:

Investigators’ clinical decision: 2 (secondary cohort)

Other: 9 (secondary cohort)

Deviate from the protocol: 6

Vehicle - reason for premature termination:

Treatment failure: 72

- *Data listing 18, End of study:*

5% LA - Reason for premature termination:

Investigators’ clinical decision: 4

Other: 19

Deviate from the protocol: 9

Vehicle - reason for premature termination:

Treatment failure: 124

Information Request for NDA 22-129

2. Study SU-02-2005

Disposition of subjects:

- *Clinical Study Report:*

Table 1.1.1:

5% L.A. – reason for premature termination:

Withdrew consent: 1

Other: 0

Deviate from the protocol: 3

Not completed the study: 14

Vehicle - reason for premature termination:

Treatment failure: 42

Not completed the study: 45

Table 1.1.2:

5% L.A. – reason for premature termination:

Withdrew consent: 0

Other: 8

Deviate from the protocol: 0

Not completed the study: 21

Vehicle - reason for premature termination:

Treatment failure: 57

Not completed the study: 66

- *Data listing 18, End of study:*

5% LA - Reason for premature termination:

Withdrew consent: 2

Other: 9

Deviate from the protocol: 2

Not completed the study: 37

Vehicle - reason for premature termination:

Treatment failure: 102

Not completed the study: 114

Information Request for NDA 22-129

Adverse Events

- *Clinical study report (p 29)*

“No subjects in the vehicle treatment group experience AEs during the study”

Table 2.1:

Vehicle: with at least one adverse event: 0

- *Data listing 16:*
Subject No 08-224-0421 (“head cold”)

3. Summary of Clinical Safety 2.7.4.

- **Table 2.7.4.1.1. Summary of the Studies Providing Safety:**

Supporting Studies:

SU-03-2005: Number of new Subjects Exposed to L.A.5% = 106

- Clinical Study report: New Subjects 47 + Vehicle (from double blind treatment failures) 68 = 115

4. Analysis of Adverse events 2.7.4.2.1:

“In the subjects treated with vehicle control, 5 of 368 subjects reported adverse events”

- The Integrated Safety Summary

Table 1- Number of subjects with Adverse Events: Vehicle N=336

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/s/

Victoria Lutwak
9/17/2007 09:58:51 AM
CSO



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-129

INFORMATION REQUEST LETTER

Target Health Inc. (b) (4)
Attention: Glen Park, Pharm.D.
Senior Director, Clinical Regulatory Affairs
261 Madison Avenue, 24th Floor
New York, NY 10016

Dear Dr. Park:

Please refer to your June 15, 2007 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lice Asphyxiator (benzyl alcohol) 5% (b) (4)

We also refer to your submission dated July 19, 2007.

We are reviewing the Chemistry, Manufacturing and Controls section of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

1. Have you manufactured any commercial size (b) (4) experimental batch? If yes, please provide any available data (i.e. COA and stability).
2. Please provide the COA for the following three clinical batches: 42083, 42084 and 43864.
3. Please follow the USP <661> monograph (Polypropylene Containers) to qualify the extractable/leachable requirements for your proposed container/closure.
4. Please revise the Drug substance specifications by removing "Current NF" from the "Assay and Related substance" test method column.

If you have any questions, call Linda Mullins Athey, Regulatory Health Project Manager for Quality, at 301-796-2096.

Sincerely,

{See appended electronic signature page}

Moo-Jhong Rhee, Ph.D.
Chief, Branch III
Pre-Marketing Assessment Division II
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

Donna Christner
8/20/2007 08:46:27 AM
signing for Dr. Moo-Jhong Rhee



**Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation III**

FACSIMILE TRANSMITTAL SHEET

DATE: August 13, 2007

To: Glen Park	From: Melinda Bauerlien, M.S. Project Manager
Company: Target Health for Summers Laboratories	Division of Dermatology & Dental Products
Fax number: (212) 681-2105	Fax number: (301) 796-9895
Phone number: (212) 681-2100	Phone number: (301) 796-2110
Subject: NDA 22-129	

Total no. of pages including cover: 4

Comments: Biostatistics Information Request. Please respond as soon as possible.

Document to be mailed: YES NO

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NDA 22-129 Biostatistics Request for information

In Study SU-01-2005 three households (Household ID: 02-110, 05-112, and 04-104) appear to randomize subjects to treatment based upon the CRF's of each of the youngest member for the household. However, only household 04-104 (randomized to vehicle) is included in the ITT population, whereas the two households randomized to L.A. 5% were NOT included in the ITT population. As the definition of the ITT population is all subjects randomized and dispensed medication, based on the subject's CRF's it is unclear why households 02-110 and 05-112 are not included in the ITT analysis. Please provide clarification as to why households 02-110 and 05-112 are not included in the ITT analysis.

The evaluation of the scalp recorded values of none (1) to severe (4) for erythema, pruritus, pyoderma, and excoriation. However, other local adverse events such as burning, numbness, stinging, etc. may have occurred. A summary or discussion of these other events do not appear in the sponsor's study report and the electronic data capture may list multiple of these events on the same row of the data set rather than as separate events. In addition, they are recorded in a verbatim like fashion without converting them to a common terminology. To facilitate the review of all adverse events of the scalp evaluation the sponsor is requested to submit an ISS data set for the skin and scalp evaluation. The following are specifications that the sponsor should use in order to construct the data set.

- When more than one term is recorded in a row of the SSEVAL data sets (e.g. numbness, burning/stinging as reported for PID 08-205-0204) then each of the terms should be recorded on separate rows.
- For terms that are currently listed in the OTHER variable of the SSEVAL data sets, these verbatim-like terms should be coded to a lower-level MedDRA term or other common terminology in order to create a nomenclature for similar adverse events. The variable to capture these other terms should be defined as TERM_OT in the ISS data set.
- The structure of the data set should contain the following information which is similar to the analysis data set AE CODED; variable names are suggested in parentheses.
 - Unique Subject ID (PID)
 - Unique Study ID (STUDY)
 - Treatment Group (TRTGRP)
 - Age of Patient (AGE)
 - Race of Patient (RACE)
 - Sex of Patient (SEX)
 - Date of Onset (ONSET)
 - Stage of Onset (STAGE)
 - Pruritus Severity: 1-4 (PRURIT)
 - Erythema Severity: 1-4 (ERYTHEM)
 - Excoriation Severity: 1-4 (EXCORT)
 - Pyoderma Severity: 1-4 (PYODERM)
 - Term for Other Events (TERM_OT)

- Other Severity: 1-4 (OTHER)

No adverse events by time of occurrence are presented in the study reports. In addition, the AE CODED analysis data set in the ISS lacks a variable to designate the time of occurrence. The analysis data set submitted in the ISS should contain a variable to denote the date of onset of the adverse event. In addition it should contain the date of enrollment as well as the date of study completion. A revised AE_CODED ISS data set should be submitted to contain these additional variables.

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/s/

Melinda Bauerlien
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CSO