DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-129

NDA ACKNOWLEDGMENT

Target Health, Inc for Summers Laboratories, Inc.
Attention: Glen Park, Pharm.D.
261 Madison Avenue, 24th Floor
New York, NY 10016

Dear Dr. Park:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Lice Asphyxiator (benzyl alcohol), 5% (b) (4)

Date of Application: June 15, 2007

Date of Receipt: June 15, 2007

Our Reference Number: NDA 22-129

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on August 14, 2007, in accordance with 21 CFR 314.101(a).

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have submitted pediatric studies with this application. Once the review of this application is complete we will notify you whether you have fulfilled the pediatric study requirement for this application.

Please cite the NDA number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatology and Dental Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any questions, call Melinda Bauerlien, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Margaret Kober, R.Ph., M.P.A.
Acting Chief, Project Management Staff
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Margaret Kober
8/1/2007 01:46:58 PM

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

FACSIMILE TRANSMITTAL SHEET

DATE: December 19, 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: 3

Comments: Response to your emailed questions dated 12/13/07

Document to be mailed: ❑ YES ☑ NO

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The following questions were asked by the sponsor in an email date December 13, 2007

1. Regarding the request for submission of all CRFs. I want to clarify whether the reviewer is requesting all CRFs for all subjects in the NDA? We can break it down by the following subsets:

    a. All Phase 3 study patients (SU-01-2005, SU-02-2005, SU-03-2005). This will be 766 CRFs and represents all safety subjects
    b. All Phase 3 Primary Cohort subjects 250 CRFs and is all primary efficacy subjects.
    c. All Phase 2 and 3 subjects 825 CRFs

    We have the Phase 3 CRFs bookmarked in pdf form and can send them by the end of the year. The Phase 2 studies are not bookmarked, but can be scanned and could also send them soon if they are required.

2. At the teleconference on Monday, the chemistry reviewer indicated that if the new bottle closure was a different material, a "benzyl alcohol uptake test" would be required and cited the USP 661 procedure. Was the reviewer referring to a test of leachable materials?

Agency's Response

Question 1:

We would like to have CFRs for all subjects in the NDA. Separating them as proposed will be nice (if possible: all Phase 2 CRFs to be different subset).

Question 2:

a. USP <661> procedure was cited for the characterization of the new material.
b. "benzyl alcohol uptake" information can be achieved by the means of two weeks (maximum duration of contact of new material with drug product) of stability data (benzyl alcohol assay) **(b) (4)**
[compare same drug product before (time zero) and after stability].

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/s/

Melinda Bauerlien
12/19/2007 11:31:57 AM
CSO

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Office/Division)*: Office of Surveillance and Epidemiology/ Division of Risk Management
Attention: Janet Anderson

FROM (*Name, Office/Division, and Phone Number of Requestor)*:
Nichelle Rashid/Regulatory Project Manager
Division of Dermatology and Dental Products
(301) 796-3904

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
11/24/08	NA	22-129	Complete Response to Approvable Letter	October 17, 2008

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
Lice Asphyxiator (benzyl alcohol) 5% lotion	Resubmission	NA	February 9, 2009

NAME OF FIRM: Sciele Pharma, Inc.

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END-OF-PHASE 2a MEETING
- ☐ END-OF-PHASE 2 MEETING
- ☒ RESUBMISSION
- ☐ SAFETY / EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☐ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

- ☐ PRIORITY P NDA REVIEW
- ☐ END-OF-PHASE 2 MEETING
- ☐ CONTROLLED STUDIES
- ☐ PROTOCOL REVIEW
- ☐ OTHER (SPECIFY BELOW):
- ☐ CHEMISTRY REVIEW
- ☐ PHARMACOLOGY
- ☐ BIOPHARMACEUTICS
- ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE 4 STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL - BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG SAFETY

- ☐ PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ NONCLINICAL

COMMENTS / SPECIAL INSTRUCTIONS: Please review the attached package insert and patient package insert. Labeling meetings have been scheduled for Februay 18 & 24, 2009. This submission is a Class 2 resubmission. The PDUFA date is April 17, 2009.
EDR Location: \\CDSESUB1\EVSPROD\NDA022129\0027
Submission Size: 12306960
Gateway Location: \\fdswa009\cderesub\inbound\ectd\1224272890882.138478@llnap01_te

SIGNATURE OF REQUESTOR

METHOD OF DELIVERY (Check one)
☒ DFS ☐ EMAIL ☐ MAIL ☐ HAND

PRINTED NAME AND SIGNATURE OF RECEIVER

PRINTED NAME AND SIGNATURE OF DELIVERER

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/s/

Nichelle Rashid
12/11/2008 03:24:55 PM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Office/Division)*: Division of Medication Errors and Technical Support (DMETS)

FROM (*Name, Office/Division, and Phone Number of Requestor)*:
Melinda Bauerlien, M.S.
Project Manager
Division of Dermatology and Dental Products

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
December 11, 2007		22-129	new NDA	June 15, 2007

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
Lice Asphyxiator (benzyl alcohol), 5% (b) (4)			December 28, 2007

NAME OF FIRM: Summers Laboratories, Inc.

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END-OF-PHASE 2a MEETING
- ☐ END-OF-PHASE 2 MEETING
- ☐ RESUBMISSION
- ☐ SAFETY / EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☒ OTHER *(SPECIFY BELOW)*:

Electronic NDA

II. BIOMETRICS

- ☐ PRIORITY P NDA REVIEW
- ☐ END-OF-PHASE 2 MEETING
- ☐ CONTROLLED STUDIES
- ☐ PROTOCOL REVIEW
- ☐ OTHER (SPECIFY BELOW):
- ☐ CHEMISTRY REVIEW
- ☐ PHARMACOLOGY
- ☐ BIOPHARMACEUTICS
- ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE 4 STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL - BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG SAFETY

- ☐ PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ NONCLINICAL

COMMENTS / SPECIAL INSTRUCTIONS: Please provide assessment of the risk for medication errors with the respect to proposed product container design changes:

- (b) (4)
- An orifice reducing plug (b) (4) and current cap (the orifice reducer we have identified (b) (4)

Also attached is the sponsor's correspondence which includes descriptions of the different routes they are thinking of taking.

SIGNATURE OF REQUESTOR Melinda Bauerlien, M.S. Project Manager 6-0906	METHOD OF DELIVERY (Check one) ☒ DFS ☐ EMAIL ☐ MAIL ☐ HAND
PRINTED NAME AND SIGNATURE OF RECEIVER	PRINTED NAME AND SIGNATURE OF DELIVERER

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

FACSIMILE TRANSMITTAL SHEET

DATE: December 4, 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: 2

Comments: Please provide CRFs from all subjects enrolled in the phase 3 clinical trials

Document to be mailed: ☐ YES ☑ NO

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/s/

Melinda Bauerlien
12/4/2007 12:55:06 PM
CSO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-129 **INFORMATION REQUEST LETTER**

Sciele Pharma, Inc.
Attention: Debra A. Hayes, RAC
Manager Regulatory Affairs
Five Concourse Parkway, Suite 1800
Atlanta, GA 30328

Dear Ms. Hayes:

Please refer to your October 17, 2008 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lice Asphyxiator (Benzyl alcohol) 5% Lotion.

We are reviewing the Clinical Pharmacology 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.

Please provide the following information for the PK Study Report # Sc-LA-08-01:

1. The analytical report for the quantitation of benzyl alcohol in the plasma that was collected during the study.

2. Individual patient listing of the PK data.

If you have any questions, call Nichelle Rashid, Regulatory Project Manager, at 301-796-3904.

Sincerely,

{See appended electronic signature page}

Margo Owens
Regulatory Project Manager Team Leader
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Margo Owens
12/3/2008 12:38:50 PM

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

FACSIMILE TRANSMITTAL SHEET

DATE: November 8, 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: 3

Comments: Comments are provided regarding your proposed tradenames

Document to be mailed: ❑ YES ☑ NO

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NDA 22-129 Comments on proposed tradenames

(b) (4) **(PRIMARY NAME)**
DDMAC objects to the proposed trade name "(b) (4) because it overstates the efficacy of the drug product, considering the drug's indication is for the treatment of head lice. '(b) (4) can be pronounced and read as two parts, (b) (4) and can be easily translated into (b) (4) Therefore, the proposed trade name misleadingly implies that the drug will provide a definitive treatment response and completely eliminate head lice. Without substantial evidence to support that (b) (4) is able to completely eliminate lice without further treatment (*i.e.* (b) (4)), the proposed trade name is misleading.

Furthermore, the proposed trade name '(b) (4) is fanciful and implies that the drug at issue or an ingredient in it has some unique effectiveness or composition when, in fact, the drug is benzyl alcohol, a common substance, the limitations of which are readily recognizable when the drug is listed by its established name [21 CFR 201.10(c)(3)].

Please note that the Federal Food Drug and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made, whether through a trade name or otherwise; this includes suggestions that a drug is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or lower incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n); 21 CFR 202.1(e)(5)(i);(e)(6)(i)].

(b) (4) **(SECONDARY NAME)**
DDMAC objects to the proposed trade name "(b) (4) because it overstates the efficacy of the drug product, considering the drug's indication is for the treatment of pediculus capitas (head lice). The proposed trade name contains two parts, (b) (4) . Therefore, the proposed trade name misleadingly suggests that (b) (4) can (b) (4) or eliminate lice from a patient's head. Without substantial evidence to support that (b) (4) is able to completely eliminate lice without further treatment, the proposed trade name is misleading.

Furthermore, the proposed trade name '(b) (4) is fanciful and implies that the drug or an ingredient in it has some unique effectiveness or composition when, in fact, the drug is benzyl alcohol, a common substance, the limitations of which are readily recognizable when the drug or ingredient is listed by its established name [21 CFR 201.10(c)(3)].

Please note that the Federal Food Drug and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made, whether through a trade name or otherwise; this includes suggestions that a drug is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or lower incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n); 21 CFR 202.1(e)(5)(i);(e)(6)(i)].

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/s/

Melinda Bauerlien
11/8/2007 12:54:52 PM
CSO

DSI CONSULT: Request for Clinical Inspections

Date: October 30, 2007

To: Constance Lewin, M.D., M.P.H, Branch Chief, GCP1, HFD-46
Joe Salewski., Branch Chief (Acting), GCP2, HFD-47

Through: Jill Lindstrom, M.D., Clinical Team Leader, Dermatology, DDDP
From: Melinda Bauerlien, M.S., Regulatory Health Project Manager
Division of Dermatology and Dental Products

Subject: Request for Inspection

I. General Information

NDA 22-129
Sponsor: Summers Laboratories, Inc.
Drug: Lice Asphyxiator (benzyl alcohol), 5% (b) (4) for the treatment of for patients infected with pediculus humanus capitis (head lice) of the scalp hair
Sponsor/Sponsor contact information (to include phone/email): Glen Park (212) 681-2100
NME: Yes
Standard

PDUFA: April 15, 2007
Action Goal Date: April 15, 2007
Inspection Summary Goal Date: February 1, 2007

II. Background Information

NDA 22-129 is a New Molecular Entity (NME) submitted for the treatment of patients infected with pediculus humanus capitis (head lice) of the scalp hair. The study reports for the NDA do not appear to accurately capture the disposition of all subjects enrolled in the clinical trial. Consequently, this affects the denominators used throughout the study reports. For the reporting of efficacy, the definition of the ITT population is all subjects designated as the primary household member who is randomized and dispensed medication. For the assessment of safety, this population should include all subjects in a household who are randomized and dispensed medication with at least one post-baseline evaluation.

III. Protocol/Site Identification

Include the Protocol Title/# for all protocols to be audited. Complete the following table.

Site # (Name,Address, Phone number, email, fax#)	Protocol #	Number of Subjects	Indication
Site 1 – Global Health Associates of Miami, Principal Investigators - Terri Meinking and Heather Woolery Lloyd, M.D. 7800 S.W. 57th Avenue - Suite 219E, South Miami, FL 33143	**SU-01-2005**	13	treatment of for patients infected with pediculus humanus capitis (head lice) of the scalp hair
Site 2 - Dermatology Research Associates, Principal Investigator - Anne Lucky, M.D. 7691 Five Mile Road, Suite 312, Cincinnati, OH 45230	**SU-01-2005**	8	treatment of for patients infected with pediculus humanus capitis (head lice) of the scalp hair
Site 6 - Arkansas Pediatric Clinic, Principal Investigator - Anton Duke, M.D. 500 S. University, Suite 200, Little Rock, AR 72205	**SU-02-2005**	15	treatment of for patients infected with pediculus humanus capitis (head lice) of the scalp hair
Site 12 – Advanced Clinical Research, LLC, Principal Investigator - Barry Collins, M.D. 2107 Martin St. South, Suite 103, Pell City, AL 35128	**SU-02-2005**	9	treatment of for patients infected with pediculus humanus capitis (head lice) of the scalp hair

IV. Site Selection/Rationale

The sites were chosen for the following reasons:
Site 1 - All household members were enrolled at the same time.
Site 2 - They have almost 100% efficacy for the active group and 0% efficacy for the vehicle group.
Site 6 - There is no difference in efficacy between the vehicle and active groups.
Site 12 - The site has unusually high efficacy for the vehicle group.

Domestic Inspections:

We have requested inspections because (please check all that apply):

____ Enrollment of large numbers of study subjects
____ High treatment responders (specify):
____ Significant primary efficacy results pertinent to decision-making
___ There is a serious issue to resolve, e.g., suspicion of fraud, scientific misconduct, significant human subject protection violations or adverse event profiles.
_X___ Other (specify): The drug is an NME and there are inconsistencies in the data provided by the sponsor.

Concurrence: Jill Lindstrom, M.D., Clinical Team Leader

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 /s/
----------------------
Jill Lindstrom
11/6/2007 01:30:01 PM
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-129 **INFORMATION REQUEST LETTER**

Target Health, Inc. for Summers Laboratories, Inc.
Attention: Glen Park, Pharm.D
Senior Director, Clinical and 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 September 21, 2007.

In your study reports, you do not appear to accurately capture the disposition of all subjects enrolled in the clinical trial. Consequently, this affects the denominators used throughout the study reports. For the reporting of efficacy, the definition of the ITT population is all subjects designated as the primary household member who is randomized and dispensed medication. For the assessment of safety, this population should include all subjects in a household who are randomized and dispensed medication with at least one post-baseline evaluation.

The subject disposition and electronic recording discrepancies are noted below. Please note that these particular subjects may be the reason for the discrepancies.

Study SU-01-2005

Data Set Name	**No. of Unique Subject ID's (`pid`)**	**Notes**
demog	314	
subjects	314	Households 02-110 and 05-112 do not contain a member with the variables `primary` and `itt` set to 1. For secondary household members in households 03-119, 05-109, and 05-112 the value of the `second` variable is not recorded as 1.
clinsum	314	
lice	305	This data set excludes the following subjects: 02-110-0108, 04-104-0104, 04-104-0204, 04-104-0304, 05-112-0113, 05-112-0213, 05-112-0313, 05-112-0413, 05-112-0513

Study SU-02-2005

Data Set Name	**No. of Unique Subject ID's (`pid`)**	**Notes**
demog	314	
subjects	314	Households 07-233 and 07-236 do not contain a member with the variables `primary` and `itt` set to 1. For secondary household members in household 08-224 the value of the `second` variable is not recorded as 1.
clinsum	314	
lice	313	This data set excludes the following subject: 07-233-0128

Based on the potential lack of inclusion of the above subjects in the study reports, we note the following discrepancies in your study reports. However, this list is not all inclusive, but those noted at the current stage of review.

1. For Study SU-01-2005, clarify data discrepancies between Clinical Study Report (10. Disposition of Patients, p 21), Statistical Tables (Table 1.1.1 and Table 1.1.2), and Data listing 18 for the number of the subjects treated with 5% L.A. who were discontinued from the study with the reason for premature termination listed as “Investigator’s clinical decision”.

2. For Study SU-01-2005, clarify data discrepancies between Clinical Study Report (10. Disposition of Patients, p 21), Statistical Tables (Table 1.1.1 and Table 1.1.2), and Data listing 18 for the number of the subjects treated with 5% L.A. who were discontinued from the study with the reason for premature termination listed as “Other reason”.

3. For Study SU-01-2005, clarify data discrepancies between Clinical Study Report (10. Disposition of Patients, p 21), Statistical Tables (Table 1.1.1 and Table 1.1.2), and Data listing 18 for the number of the subjects treated with 5% L.A. who deviated from the protocol.

4. For Study SU-01-2005, clarify data discrepancies between Clinical Study Report (10. Disposition of Patients, p 21), Statistical Tables (Table 1.1.1 and Table 1.1.2), and Data listing 18 for the number of the subjects treated with Vehicle who were discontinued from the study with the reason for premature termination listed as “Treatment failure”.

5. For Study SU-02-2005, clarify data discrepancies between Clinical Study Report (10. Disposition of Patients, p 21), Statistical Tables (Table 1.1.1 and Table 1.1.2), and Data listing 18 for the number of the subjects treated with 5% L.A. who were discontinued from the study with the reason for premature termination listed as “Withdrew consent”.

6. For Study SU-02-2005, clarify data discrepancies between Clinical Study Report (10. Disposition of Patients, p 21), Statistical Tables (Table 1.1.1 and Table 1.1.2), and Data listing 18 for the number of the subjects treated with 5% L.A. who were discontinued from the study with the reason for premature termination listed as “Other reason”.

7. For Study SU-02-2005, clarify data discrepancies between Clinical Study Report (10. Disposition of Patients, p 21), Statistical Tables (Table 1.1.1 and Table 1.1.2), and Data listing 18 for the number of the subjects treated with 5% L.A. who deviated from the protocol.

8. For Study SU-01-2005, clarify data discrepancies between Statistical Tables (Table 1.1.1 and Table 1.1.2), and Data listing 18 for the number of the subjects treated with 5% L.A. who did not complete the study.

9. For Study SU-02-2005, clarify data discrepancies between Clinical Study Report (10. Disposition of Patients, p 21), Statistical Tables (Table 1.1.1 and Table 1.1.2), and Data listing 18 for the number of the subjects treated with Vehicle who were discontinued from the study with the reason for premature termination listed as “Treatment failure”.

10. For Study SU-02-2005, clarify data discrepancies between Statistical Tables (Table 1.1.1 and Table 1.1.2), and Data listing 18 for the number of the subjects treated with Vehicle who did not complete the study.

11. For Study SU-02-2005, clarify data discrepancies in reporting adverse events between the Clinical Study Report (12.4. Adverse Events, p 29) and Data listing 16.

12. For study SU-03-2005, clarify number of New Subjects Exposed to 5% L.A. [data discrepancies between Summary of Clinical Safety (2.7.4.; Table 2.7.4.1.1- Summary of the Studies Providing Safety) and Clinical Study Report].

13. Clarify the number of subjects treated with vehicle control [data discrepancies for the number of the subjects that were treated with vehicle reported in Section 2.7.4 (Analysis of Adverse Events)/ISS (5.3.5.3.2.2.1, p10) and Table 1 – Number of the Subjects with Adverse Events].

14. Clarify number of the severe adverse events (data discrepancies between 2.7.4 Summary of Clinical Safety, p 10, ISS Table 2 and ISS Table 5.3.5.3.2.4.2, p 17).

15. Clarify data from Table 2.7.4.4.1(1) Frequency of Shifts from Baseline in Severity of Scalp Signs/Symptoms.

16. Clarify data from Table (2.7.3.2.)1 Summary of Studies Providing Efficacy Information (Number of the subjects in Secondary Cohort).

17. Clarify data discrepancies summarized in Table (2.7.3.3.1)1 - Baseline Scalp Signs and Symptoms Severity and Table (2.7.3.2.)1 - Summary of Studies Providing Efficacy Information for the number of the subjects without baseline Pruritus, Erythema, Pyoderma and Excoriation.

In addition, we have the following information request from Chemistry, Manufacturing and Controls.

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.

19. 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.

If you have any questions, call Melinda Bauerlien, M.S., Project Manger, at 301-796-0906.

Sincerely,

Jill Lindstrom, M.D.
Clinical Team Leader, Dermatology
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Jill Lindstrom
11/5/2007 02:59:23 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-129

Sciele® Pharma, Inc.
Attention: Debra Hayes, RAC, Manager Regulatory Affairs
Five Concourse Parkway
Suite 1800
Atlanta, GA 30328

Dear Ms. Hayes:

We acknowledge receipt on October 17, 2008 of your October 17, 2008 resubmission to your new drug application for TRADENAME Lice Asphyxiator (benzyl alcohol) 5% Lotion.

We consider this a complete, class 2 response to our July 14, 2008, action letter. Therefore, the user fee goal date is April 17, 2009.

If you have any question, call me at (301) 796-3904.

Sincerely,

{See appended electronic signature page}

Nichelle E. Rashid
Regulatory Health Project Manager
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Nichelle Rashid
10/31/2008 12:31:58 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

FILING COMMUNICATION

NDA 22-129

Target Health, Inc. for Summers Laboratories, Inc.
Attention: Glen Park, Pharm.D.
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 have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, this application was filed under section 505(b) of the Act on August 14, 2007, in accordance with 21 CFR 314.101(a).

Due to the reliance on literature information to satisfy the repeat dose systemic toxicity and genotoxicity informational needs for benzyl alcohol, we have determined that your application qualifies for review under 505(b)(2).

In our filing review, we have identified the following potential review issues:

1. Trade dressings for labels are not provided.

2. Drug substance stability data under ICH storage conditions are inadequate.

3. Supporting information for the proposed dosage form nomenclature is inadequate.

We are providing the above comments to give you preliminary notice of potential review issues. Our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review. Issues may be added, deleted, expanded upon, or modified as we review the application.

We also request that you submit the following information:

1. Provide samples for labels with proposed trade dressing.

2. Update drug substance stability data for stability studies conducted under ICH storage conditions.

3. Provide the rheograms (viscosity versus shear rate and shear stress versus shear rate) for the formulation.

Please respond only to the above requests for additional information. While we anticipate that any response submitted in a timely manner will be reviewed during this review cycle, such review decisions will be made on a case-by-case basis at the time of receipt of the submission.

If you have any questions, call Melinda Bauerlien, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Susan J. Walker, M.D.
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Susan Walker
8/22/2007 06:24:03 PM

MEMORANDUM OF TELECON

DATE: July 18, 2008

APPLICATION NUMBER: NDA 22-129 - Benzyl Alcohol Lotion 5%

BETWEEN:

Name: Stephanie Cooke, MS, RAC
Vice President, Regulatory and Quality Assurance
Phone: (678) 459-1405
Representing: Sciele Pharma, Inc.

AND

Name: Maria R. Walsh, RN, MS
Project Management Officer
Office of Drug Evaluation III

SUBJECT: Timing of resubmission following approvable action

BACKGROUND: NDA 22-129, benzyl alcohol lotion 5%, was submitted on June 15, 2007 for the treatment of head lice and was approvable on July 14, 2008. The applicant was notified on July 11, 2008 of the following clinical pharmacology approvability issue:

> The in-vivo pharmacokinetic study SU-01-2007 resulted in a number of plasma concentrations of benzyl alcohol. While the median value of all 32 positive samples was ~2.7ug/mL, the upper quartile of them were above 48 ug/mL. Because the plasma concentrations of benzyl alcohol observed are sporadic, it is difficult to adequately interpret the observed high concentrations of benzyl alcohol. Since these plasma concentrations of benzyl alcohol are used to support the systemic safety of the drug product, it is important that you provide further clarification (e.g. are they true representative concentrations) as to why these plasma concentrations were observed and their potential safety impact, including but not limited to, a discussion vis a vis the reported association of plasma levels of benzyl alcohol and infant gasping syndrome.

In addition, the sponsor was advised that revised labeling and satisfactory resolution of the deficiencies regarding the inspection of the manufacturing facility for the drug substance were required before this application may be approved.

TODAY'S CALL: Ms. Cooke called and inquired about the timing of the response to the approvable letter. She asked if the sponsor could respond to the clinical pharmacology issue and labeling issues before the manufacturing facility was re-inspected. I advised Ms. Cooke that the sponsor could submit this information at any time but that the application would not be considered resubmitted until we received a letter from the sponsor informing us that the facility inspection was completed. This letter, together with the response to the clinical pharmacology

and labeling issues, would constitute a resubmission (most likely Class 1) and would trigger a new review cycle and due date. Ms. Cooke indicated she understood and the call was then concluded.

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/s/

Maria Walsh
7/18/2008 02:49:31 PM
CSO

MEMORANDUM OF TELECON

DATE: June 26, 2008

APPLICATION NUMBER: NDA 22-129 TRADENAME (benzyl alcohol) Lotion 5%

BETWEEN:

Name: Stephanie Cooke, MS, RAC, VP Regulatory and Quality Assurance
Phone: (404) 271-2307
Representing: Sciele Pharma, Inc.

AND

Name: Maria R. Walsh, RN, MS, Project Management Officer
Division of Dermatology and Dental Products

SUBJECT: API Facility Inspection/Proposed Tradenames

BACKGROUND: NDA 22-129 was submitted on June 15, 2007 for Lice Asphyxiator (benzyl alcohol) (b) (4) 5% for the treatment of head lice.

The sponsor submitted the proposed tradenames, (b) (4) and (b) (4) on December 12, 2007. Loretta Holmes, Division of Medication Error Prevention (DMEDP), communicated to me in a June 23, 2008 e-mail that both proposed tradenames are likely to be unacceptable (draft review pending signature) and advised me to notify the sponsor and ask them to submit new proposed tradenames for this product.

The manufacturing facility for the API (b) (4) received a withhold recommendation on March 18, 2008 from the Office of Compliance and a 483 was issued on May 12, 2008. The sponsor is working with the manufacturer to address the 483 issues and provided letters of authorization from the manufacturer allowing the sponsor to discuss issues surrounding DMF (b) (4), API/Benzyl Alcohol NF (b) (4) with FDA. (b) (4), (b) (4) Office, in an e-mail dated June 26, 2008, asked me for clarification concerning DMF (b) (4). She said that if a re-inspection of the facility is acceptable, the product will be cleared for topical use, (b) (4), and wanted to be sure that this is the understanding of the sponsor and the manufacturer.

TODAY CALL: I called Ms. Cooke and relayed that the proposed tradenames, (b) (4) and (b) (4) are not acceptable. I advised her to submit new proposed tradenames as soon as possible and she agreed.

I asked Ms. Cooke why the referenced DMF for the NDA is for Benzyl Alcohol – (b) (4) when the proposed product is to be used topically. She said that the manufacturer wanted to use

the (b) (4) for this product. I explained that if the re-inspection of the API manufacturing facility is acceptable, it would be cleared for this topical product and not for a future (b) (4) product. She confirmed that this was the understanding of the sponsor and the manufacturer. The call was then concluded.

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/s/

Maria Walsh
6/27/2008 12:32:12 PM
CSO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-129

Sciele Pharma, inc.
Attention: Debra A. Hayes, RAC
Five Concourse Parkway, Suite 1800
Atlanta, Georgia 30328

Dear Ms. Hayes:

We acknowledge receipt on November 19, 2007, of your November 19, 2007, correspondence notifying the Food and Drug Administration of the change of ownership of the following new drug application (NDA):

Name of Drug Product: TRADENAME (benzyl alcohol) Lotion 5%

NDA Number: 22-129

Name of New Applicant: Sciele Pharma, Inc.

Name of Previous Applicant: Summers Laboratories, Inc.

Under 21 CFR 314.72, the following information is required to complete the change of ownership procedure:

1. The date the new ownership became effective.

2. A new Form FDA 356h signed by an authorized agent or official of the company.

3. Evidence of the new ownership of the NDA. This may be in the form of a letter or other documentation from the former applicant to show that all rights have been assigned or transferred to you. Patent or copyright ownership is not acceptable evidence of ownership of the NDA.

4. A commitment to all agreements, promises, and conditions made by the former owner and contained in the application.

5. Assurance that you were provided a complete copy of the previous owner's NDA.

6. Labeling (draft or final) to show the changes in name and address of the manufacturer, packer, or distributor of the drug.

We request that you notify your suppliers and contractors who have DMFs referenced by your application of the change in ownership so that they can submit a new letter of authorization (LOA) to their Drug Master File(s).

You are responsible for any correspondence outstanding as of the effective date of the transfer.

Please cite the NDA number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatology and Dental Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any questions, call me at (301) 796-1017.

Sincerely,

{See appended electronic signature page}

Maria R. Walsh, RN, MS
Project Management Officer
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc: Summers Laboratories, Inc.
Attention: Michael J. Precopio
103 G.P. Clement Drive
Collegeville, PA 19426

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/s/

Maria Walsh
6/25/2008 07:27:31 PM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Office/Division)*: OND/PMHS

FROM (*Name, Office/Division, and Phone Number of Requestor)*:
ODE III/DDDP
Maria Walsh, ODE III IO - 796-1017

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
6/12/08		22-129	Draft Package Insert	

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
Lice Asphyxiator Lotion		1S	6/19/08

NAME OF FIRM: Sciele Pharma, Inc.

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END-OF-PHASE 2a MEETING
- ☐ END-OF-PHASE 2 MEETING
- ☐ RESUBMISSION
- ☐ SAFETY / EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☒ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

- ☐ PRIORITY P NDA REVIEW
- ☐ END-OF-PHASE 2 MEETING
- ☐ CONTROLLED STUDIES
- ☐ PROTOCOL REVIEW
- ☐ OTHER (SPECIFY BELOW):
- ☐ CHEMISTRY REVIEW
- ☐ PHARMACOLOGY
- ☐ BIOPHARMACEUTICS
- ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE 4 STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL - BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG SAFETY

- ☐ PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ NONCLINICAL

COMMENTS / SPECIAL INSTRUCTIONS: Please consider the FDA-revised draft package insert (dated 6-11-08) for this pending NDA and provide any revisions.

SIGNATURE OF REQUESTOR

METHOD OF DELIVERY (Check one)
☒ DFS ☐ EMAIL ☐ MAIL ☐ HAND

PRINTED NAME AND SIGNATURE OF RECEIVER

PRINTED NAME AND SIGNATURE OF DELIVERER

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/s/

Maria Walsh
6/12/2008 01:14:21 PM

NDA REGULATORY FILING REVIEW
(Including Memo of Filing Meeting)

NDA # 22-129 Supplement # Efficacy Supplement Type SE-

Proprietary Name: (b) (4) Lice Asphyxiator
Established Name: benzyl alcohol
Strengths: 5% (b) (4)

Applicant: Sciele Pharma
Agent for Applicant (if applicable):
Date of Application: June 15, 2007
Date of Receipt: June 15, 2007
Date clock started after UN: N/A
Date of Filing Meeting: July 31, 2007
Filing Date: August 14, 2007
Action Goal Date (optional): April 15, 2008 User Fee Goal Date: April 15, 2008

Indication(s) requested: for patients infected with Pediculus humanus capitas (head lice and their ova) of the scalp hair

Type of Original NDA: (b)(1) ☐ (b)(2) ☒
AND (if applicable)
Type of Supplement: (b)(1) ☐ (b)(2) ☐

NOTE:
(1) If you have questions about whether the application is a 505(b)(1) or 505(b)(2) application, see Appendix A. A supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2). If the application or efficacy supplement is a (b)(2), complete Appendix B.

Review Classification: S ☒ P ☐
Resubmission after withdrawal? ☐ Resubmission after refuse to file? ☐
Chemical Classification: (1,2,3 etc.) 1
Other (orphan, OTC, etc.) N/A

Form 3397 (User Fee Cover Sheet) submitted: YES ☒ NO ☐

User Fee Status: Paid ☒ Exempt (orphan, government) ☐
Waived (e.g., small business, public health) ☐

NOTE: *If the NDA is a 505(b)(2) application, and the applicant did not pay a fee in reliance on the 505(b)(2) exemption (see box 7 on the User Fee Cover Sheet), confirm that a user fee is not required by contacting the User Fee staff in the Office of Regulatory Policy. The applicant is required to pay a user fee if: (1) the product described in the 505(b)(2) application is a new molecular entity or (2) the applicant claims a new indication for a use that that has not been approved under section 505(b). Examples of a new indication for a use include a new indication, a new dosing regime, a new patient population, and an Rx-to-OTC switch. The best way to determine if the applicant is claiming a new indication for a use is to compare the applicant's proposed labeling to labeling that has already been approved for the product described in the application. Highlight the differences between the proposed and approved labeling. If you need assistance in determining if the applicant is claiming a new indication for a use, please contact the User Fee staff.*

- Is there any 5-year or 3-year exclusivity on this active moiety in any approved (b)(1) or (b)(2) application? YES ☐ NO ☒
  If yes, explain:

Note: If the drug under review is a 505(b)(2), this issue will be addressed in detail in appendix B.

- Does another drug have orphan drug exclusivity for the same indication? YES ☐ NO ☒

- If yes, is the drug considered to be the same drug according to the orphan drug definition of sameness [21 CFR 316.3(b)(13)]?
  N/A YES ☐ NO ☐

  If yes, consult the Director, Division of Regulatory Policy II, Office of Regulatory Policy (HFD-007).

- Is the application affected by the Application Integrity Policy (AIP)? YES ☐ NO ☒
  If yes, explain:

- If yes, has OC/DMPQ been notified of the submission? N/A YES ☐ NO ☐

- Does the submission contain an accurate comprehensive index? YES ☒ NO ☐
  If no, explain:

- Was form 356h included with an authorized signature? YES ☒ NO ☐
  If foreign applicant, both the applicant and the U.S. agent must sign.

- Submission complete as required under 21 CFR 314.50? YES ☒ NO ☐
  If no, explain:

- Answer 1, 2, or 3 below (do not include electronic content of labeling as an partial electronic submission).

1. This application is a paper NDA YES ☐

2. This application is an eNDA or combined paper + eNDA YES ☒
   This application is: All electronic ☒ Combined paper + eNDA ☐
   This application is in: NDA format ☐ CTD format ☒
   Combined NDA and CTD formats ☐

   Does the eNDA, follow the guidance?
   (http://www.fda.gov/cder/guidance/2353fnl.pdf) YES ☒ NO ☐

   If an eNDA, all forms and certifications must be in paper and require a signature.

   If combined paper + eNDA, which parts of the application were submitted in electronic format?

   Additional comments:

3. This application is an eCTD NDA. YES ☒
   If an eCTD NDA, all forms and certifications must either be in paper and signed or be electronically signed.

   Additional comments:

- Patent information submitted on form FDA 3542a? YES ☒ NO ☐

- Exclusivity requested? YES, 5 Years NO ☐
  NOTE: *An applicant can receive exclusivity without requesting it; therefore, requesting exclusivity is not required.*

- Correctly worded Debarment Certification included with authorized signature? YES ☒ NO ☐
  If foreign applicant, both the applicant and the U.S. Agent must sign the certification.

  NOTE: *Debarment Certification should use wording in FD&C Act section 306(k)(1) i.e., "[Name of applicant] 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." Applicant may not use wording such as "To the best of my knowledge . . . ."*

- Are the required pediatric assessment studies and/or deferral/partial waiver/full waiver of pediatric studies (or request for deferral/partial waiver/full waiver of pediatric studies) included?
  *Waiver request for ages 1-6 months was not submitted. It has been requested from the sponsor
  YES ☐ NO ☒

- If the submission contains a request for deferral, partial waiver, or full waiver of studies, does the application contain the certification required under FD&C Act sections 505B(a)(3)(B) and (4)(A) and (B)? YES ☐ NO ☐

- Is this submission a partial or complete response to a pediatric Written Request? YES ☐ NO ☒

  If yes, contact PMHT in the OND-IO

- Financial Disclosure forms included with authorized signature? YES ☒ NO ☐
  (Forms 3454 and/or 3455 must be included and must be signed by the APPLICANT, not an agent.)
  NOTE: *Financial disclosure is required for bioequivalence studies that are the basis for approval.*

- Field Copy Certification (that it is a true copy of the CMC technical section) YES ☒ NO ☐

- PDUFA and Action Goal dates correct in tracking system? YES ☒ NO ☐
  If not, have the document room staff correct them immediately. These are the dates EES uses for calculating inspection dates.

- Drug name and applicant name correct in COMIS? If not, have the Document Room make the corrections. Ask the Doc Rm to add the established name to COMIS for the supporting IND if it is not already entered.

- List referenced IND numbers: 50,076

- Are the trade, established/proper, and applicant names correct in COMIS? YES ☒ NO ☐
  If no, have the Document Room make the corrections.

- End-of-Phase 2 Meeting(s)? Date(s) 9/9/04 NO ☐
  If yes, distribute minutes before filing meeting.

- Pre-NDA Meeting(s)? Date(s) 3/12/07 NO ☐
  If yes, distribute minutes before filing meeting.

- Any SPA agreements? Date(s) 5/18/05 NO ☐
  If yes, distribute letter and/or relevant minutes before filing meeting.

Project Management

- If Rx, was electronic Content of Labeling submitted in SPL format? YES ☒ NO ☐
  If no, request in 74-day letter.

- If Rx, for all new NDAs/efficacy supplements submitted on or after 6/30/06:
  Was the PI submitted in PLR format? YES ☒ NO ☐

  If no, explain. Was a waiver or deferral requested before the application was received or in the submission? If before, what is the status of the request:

- If Rx, all labeling (PI, PPI, MedGuide, carton and immediate container labels) has been consulted to DDMAC? YES ☒ NO ☐

- If Rx, trade name (and all labeling) consulted to OSE/DMETS? YES ☒ NO ☐

- If Rx, MedGuide and/or PPI (plus PI) consulted to ODE/DSRCS?
  N/A ☒ YES ☐ NO ☐

- Risk Management Plan consulted to OSE/IO? N/A ☒ YES ☐ NO ☐

- If a drug with abuse potential, was an Abuse Liability Assessment, including a proposal for scheduling submitted? NA ☒ YES ☐ NO ☐

If Rx-to-OTC Switch or OTC application:

- Proprietary name, all OTC labeling/packaging, and current approved PI consulted to OSE/DMETS? YES ☐ NO ☐

- If the application was received by a clinical review division, has DNPCE been notified of the OTC switch application? Or, if received by DNPCE, has the clinical review division been notified? YES ☐ NO ☐

Clinical

- If a controlled substance, has a consult been sent to the Controlled Substance Staff?
  YES ☐ NO ☐

Chemistry

- Did applicant request categorical exclusion for environmental assessment? YES ☒ NO ☐
  If no, did applicant submit a complete environmental assessment? YES ☐ NO ☐
  If EA submitted, consulted to EA officer, OPS? YES ☐ NO ☐

- Establishment Evaluation Request (EER) submitted to DMPQ? YES ☒ NO ☐

- If a parenteral product, consulted to Microbiology Team? YES ☐ NO ☐

ATTACHMENT

MEMO OF FILING MEETING

DATE: July 31, 2007

NDA #: 22-129

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

APPLICANT: Summers Laboratories, Inc.

BACKGROUND: Lice Asphyxiator (benzyl alcohol) 5% (b) (4) is a 505(b)(2) application and is a New Molecular Entity indicated for patients infected with pediculus humanus capitas (head lice) of the scalp hair.

ATTENDEES: Susan Walker, M.D. and the reviewers listed below.

ASSIGNED REVIEWERS (including those not present at filing meeting) :

Discipline/Organization	Reviewer	Team Leader
Medical:	Gordana Diglisic	Jill Lindstrom
Secondary Medical:	n/a	
Statistical:	Mat Soukup	Mohamed Alosh
Pharmacology:	Barbara Hill	Paul Brown
Statistical Pharmacology:	n/a	
Chemistry:	Tarun Mehta	Shulin Ding
Environmental Assessment (if needed):	n/a	
Biopharmaceutical:	Abi Adebowale	Sue-Chih Lee
Microbiology, sterility:	n/a	
Microbiology, clinical (for antimicrobial products only):	n/a	
DSI:	n/a	
OPS:	n/a	
Regulatory Project Management:	Melinda Bauerlien	
Other Consults:		

Per reviewers, are all parts in English or English translation? YES ☒ NO ☐
If no, explain:

CLINICAL FILE ☒ REFUSE TO FILE ☐

- Clinical site audit(s) needed? YES ☐ NO ☒
  If no, explain:
- Advisory Committee Meeting needed? YES, date if known _____ NO ☒

- If the application is affected by the AIP, has the division made a recommendation regarding whether or not an exception to the AIP should be granted to permit review based on medical necessity or public health significance?
  N/A ☒ YES ☐ NO ☐

CLINICAL MICROBIOLOGY N/A ☒ FILE ☐ REFUSE TO FILE ☐

STATISTICS N/A ☐ FILE ☒ REFUSE TO FILE ☐

BIOPHARMACEUTICS FILE ☒ REFUSE TO FILE ☐

- Biopharm. study site audits(s) needed? YES ☐ NO ☒

PHARMACOLOGY/TOX N/A ☐ FILE ☒ REFUSE TO FILE ☐

- GLP audit needed? YES ☐ NO ☒

CHEMISTRY FILE ☒ REFUSE TO FILE ☐

- Establishment(s) ready for inspection? YES ☒ NO ☐
- Sterile product? YES ☐ NO ☒
  If yes, was microbiology consulted for validation of sterilization? YES ☐ NO ☐

ELECTRONIC SUBMISSION:
Any comments:

REGULATORY CONCLUSIONS/DEFICIENCIES:
(Refer to 21 CFR 314.101(d) for filing requirements.)

☐ The application is unsuitable for filing. Explain why:

☒ The application, on its face, appears to be well-organized and indexed. The application appears to be suitable for filing.

☐ No filing issues have been identified.

☒ Filing issues to be communicated by Day 74. List (optional):

1. Trade dressings for labels are not provided.
2. Drug substance stability data under ICH storage conditions are inadequate.
3. Supporting information for the proposed dosage form nomenclature is inadequate.

ACTION ITEMS:

1. ☐ Ensure that the review and chemical classification codes, as well as any other pertinent classification codes (e.g., orphan, OTC) are correctly entered into COMIS.

2. ☐ If RTF, notify everybody who already received a consult request of RTF action. Cancel the EER.

3. ☐ If filed and the application is under the AIP, prepare a letter either granting (for signature by Center Director) or denying (for signature by ODE Director) an exception for review.

4. ☐ If filed, complete the Pediatric Page at this time. (If paper version, enter into DFS.)

5. ☒ Convey document filing issues/no filing issues to applicant by Day 74.

Melinda Bauerlien
Regulatory Project Manager

Appendix A to NDA Regulatory Filing Review

NOTE: The term "original application" or "original NDA" as used in this appendix denotes the NDA submitted. It does not refer to the reference drug product or "reference listed drug."

An original application is likely to be a 505(b)(2) application if:

(1) it relies on published literature to meet any of the approval requirements, and the applicant does not have a written right of reference to the underlying data. If published literature is cited in the NDA but is not necessary for approval, the inclusion of such literature will not, in itself, make the application a 505(b)(2) application,
(2) it relies for approval on the Agency's previous findings of safety and efficacy for a listed drug product and the applicant does not own or have right to reference the data supporting that approval, or
(3) it relies on what is "generally known" or "scientifically accepted" about a class of products to support the safety or effectiveness of the particular drug for which the applicant is seeking approval. (Note, however, that this does not mean *any* reference to general information or knowledge (e.g., about disease etiology, support for particular endpoints, methods of analysis) causes the application to be a 505(b)(2) application.)

Types of products for which 505(b)(2) applications are likely to be submitted include: fixed-dose combination drug products (e.g., heart drug and diuretic (hydrochlorothiazide) combinations); OTC monograph deviations(see 21 CFR 330.11); new dosage forms; new indications; and, new salts.

An efficacy supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2).

An efficacy supplement is a 505(b)(1) supplement if the supplement contains all of the information needed to support the approval of the change proposed in the supplement. For example, if the supplemental application is for a new indication, the supplement is a 505(b)(1) if:

(1) The applicant has conducted its own studies to support the new indication (or otherwise owns or has right of reference to the data/studies),

(2) No additional information beyond what is included in the supplement or was embodied in the finding of safety and effectiveness for the original application or previously approved supplements is needed to support the change. For example, this would likely be the case with respect to safety considerations if the dose(s) was/were the same as (or lower than) the original application, and.

(3) All other “criteria” are met (e.g., the applicant owns or has right of reference to the data relied upon for approval of the supplement, the application does not rely for approval on published literature based on data to which the applicant does not have a right of reference).

An efficacy supplement is a 505(b)(2) supplement if:

(1) Approval of the change proposed in the supplemental application would require data beyond that needed to support our previous finding of safety and efficacy in the approval of the

original application (or earlier supplement), and the applicant has not conducted all of its own studies for approval of the change, or obtained a right to reference studies it does not own. For example, if the change were for a new indication AND a higher dose, we would likely require clinical efficacy data and preclinical safety data to approve the higher dose. If the applicant provided the effectiveness data, but had to rely on a different listed drug, or a new aspect of a previously cited listed drug, to support the safety of the new dose, the supplement would be a 505(b)(2),

(2) The applicant relies for approval of the supplement on published literature that is based on data that the applicant does not own or have a right to reference. If published literature is cited in the supplement but is not necessary for approval, the inclusion of such literature will not, in itself, make the supplement a 505(b)(2) supplement, or

(3) The applicant is relying upon any data they do not own or to which they do not have right of reference.

If you have questions about whether an application is a 505(b)(1) or 505(b)(2) application, consult with your ODE's Office of Regulatory Policy representative.

Appendix B to NDA Regulatory Filing Review
Questions for 505(b)(2) Applications

1. Does the application reference a listed drug (approved drug)? YES ☐ NO ☒

*If "**No**," skip to question 3.*

2. Name of listed drug(s) referenced by the applicant (if any) and NDA/ANDA #(s):

3. Is this application for a drug that is an "old" antibiotic (as described in the draft guidance implementing the 1997 FDAMA provisions? (Certain antibiotics are not entitled to Hatch-Waxman patent listing and exclusivity benefits.)
YES ☐ NO ☒

*If "**Yes**," skip to question 7.*

4. Is this application for a recombinant or biologically-derived product?
YES ☐ NO ☒

*If "**Yes** "contact your ODE's Office of Regulatory Policy representative.*

5. The purpose of the questions below (questions 5 to 6) is to determine if there is an approved drug product that is equivalent or very similar to the product proposed for approval that should be referenced as a listed drug in the pending application.

   (a) Is there a pharmaceutical equivalent(s) to the product proposed in the 505(b)(2) application that is already approved?
   YES ☐ NO ☒

   (***Pharmaceutical equivalents*** are drug products in identical dosage forms that: **(1)** contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, or, in the case of modified release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; **(2)** do not necessarily contain the same inactive ingredients; **and** **(3)** meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates. (21 CFR 320.1(c))

*If "**No**," to (a) skip to question 6. Otherwise, answer part (b and (c)).*

   (b) Is the pharmaceutical equivalent approved for the same indication for which the 505(b)(2) application is seeking approval? YES ☐ NO ☐

   (c) Is the approved pharmaceutical equivalent(s) cited as the listed drug(s)? YES ☐ NO ☐

*If "**Yes**," (c), list the pharmaceutical equivalent(s) and proceed to question 6.*

*If "**No**," to (c) list the pharmaceutical equivalent and contact your ODE's Office of Regulatory Policy representative.*
Pharmaceutical equivalent(s):

6. (a) Is there a pharmaceutical alternative(s) already approved? YES ☐ NO ☒

(***Pharmaceutical alternatives*** are drug products that contain the identical therapeutic moiety, or its precursor, but not necessarily in the same amount or dosage form or as the same salt or ester. Each such drug product individually meets either the identical or its own respective compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times and/or dissolution rates. (21 CFR 320.1(d)) Different dosage forms and strengths within a product line by a single manufacturer are thus pharmaceutical alternatives, as are extended-release products when compared with immediate- or standard-release formulations of the same active ingredient.)

*If "**No**," to (a) skip to question 7. Otherwise, answer part (b and (c)).*

(*b*) Is the pharmaceutical alternative approved for the same indication for which the 505(b)(2) application is seeking approval? YES ☐ NO ☐

(c) Is the approved pharmaceutical alternative(s) cited as the listed drug(s)? YES ☐ NO ☒

*If "**Yes**," to (c), proceed to question 7.*

NOTE: *If there is more than one pharmaceutical alternative approved, consult your ODE's Office of Regulatory Policy representative to determine if the appropriate pharmaceutical alternatives are referenced.*

*If "**No**," to (c), list the pharmaceutical alternative(s) and contact your ODE's Office of Regulatory Policy representative. Proceed to question 7.*

Pharmaceutical alternative(s):

7. (a) Does the application rely on published literature necessary to support the proposed approval of the drug product (i.e. is the published literature necessary for the approval)?
YES ☒ NO ☐

*If "**No**," skip to question 8. Otherwise, answer part (b).*

(b) Does any of the published literature cited reference a specific (e.g. brand name) product? Note that if yes, the applicant will be required to submit patent certification for the product, see question 12. No

8. Describe the change from the listed drug(s) provided for in this (b)(2) application (for example, "This application provides for a new indication, otitis media" or "This application provides for a change in dosage form, from capsules to solution"). n/a

9. Is the application for a duplicate of a listed drug and eligible for approval under section 505(j) as an ANDA? (Normally, FDA may refuse-to-file such NDAs (see 21 CFR 314.101(d)(9)). YES ☐ NO ☒

10. Is the application for a duplicate of a listed drug whose only difference is that the extent to which the active ingredient(s) is absorbed or otherwise made available to the site of action less than that of the reference listed drug (RLD)? (See 314.54(b)(1)). If yes, the application may be refused for filing under 21 CFR 314.101(d)(9)). YES ☐ NO ☒

11. Is the application for a duplicate of a listed drug whose only difference is YES ☐ NO ☒

that the rate at which the product's active ingredient(s) is absorbed or made available to the site of action is unintentionally less than that of the RLD (see 21 CFR 314.54(b)(2))? If yes, the application may be refused for filing under 21 CFR 314.101(d)(9).

12. Are there certifications for each of the patents listed in the Orange Book for the listed drug(s) referenced by the applicant (see question #2)? (This is different from the patent declaration submitted on form FDA 3542 and 3542a.) N/A ☐ YES NO ☐

13. Which of the following patent certifications does the application contain? (Check all that apply <u>and</u> identify the patents to which each type of certification was made, as appropriate.)

☒ Not applicable (e.g., solely based on published literature. See question # 7

☐ 21 CFR 314.50(i)(1)(i)(A)(1): The patent information has not been submitted to FDA. (Paragraph I certification)
Patent number(s):

☐ 21 CFR 314.50(i)(1)(i)(A)(2): The patent has expired. (Paragraph II certification)
Patent number(s):

☐ 21 CFR 314.50(i)(1)(i)(A)(3): The date on which the patent will expire. (Paragraph III certification)
Patent number(s):

☐ 21 CFR 314.50(i)(1)(i)(A)(4): The patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted. (Paragraph IV certification)
Patent number(s):

NOTE: *IF FILED, and if the applicant made a "Paragraph IV" certification [21 CFR 314.50(i)(1)(i)(A)(4)], the applicant must* ***subsequently*** *submit a signed certification stating that the NDA holder and patent owner(s) were notified the NDA was filed [21 CFR 314.52(b)]. The applicant must also submit documentation showing that the NDA holder and patent owner(s) received the notification [21 CFR 314.52(e)]. OND will contact you to verify that this documentation was received.*

☐ 21 CFR 314.50(i)(3): Statement that applicant has a licensing agreement with the patent owner (must also submit certification under 21 CFR 314.50(i)(1)(i)(A)(4) above).
Patent number(s):

☐ Written statement from patent owner that it consents to an immediate effective date upon approval of the application.
Patent number(s):

☐ 21 CFR 314.50(i)(1)(ii): No relevant patents.

☐ 21 CFR 314.50(i)(1)(iii): The patent on the listed drug is a method of use patent and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent as described in the corresponding use code in the Orange Book. Applicant must provide a statement that the method of use patent does not claim any of the proposed indications. (Section viii statement)
Patent number(s):

14. Did the applicant:

- Identify which parts of the application rely on the finding of safety and effectiveness for a listed drug or published literature describing a listed drug or both? For example, pharm/tox section of application relies on finding of preclinical safety for a listed drug.

N/A ☐ NO ☐

YES

*If "**Yes**," what is the listed drug product(s) and which sections of the 505(b)(2) application rely on the finding of safety and effectiveness or on published literature about that listed drug*
Was this listed drug product(s) referenced by the applicant? (see question # 2)

YES ☐ NO ☒

- Submit a bioavailability/bioequivalence (BA/BE) study comparing the proposed product to the listed drug(s)?

N/A ☒ YES ☐ NO ☐

15. (a) Is there unexpired exclusivity on this listed drug (for example, 5 year, 3 year, orphan or pediatric exclusivity)? Note: this information is available in the Orange Book.

N/A ☐ NO ☐

YES

If "**Yes**," please list:

Application No.	Product No.	Exclusivity Code	Exclusivity Expiration

---

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/s/

Melinda Bauerlien
6/6/2008 01:34:42 PM
CSO

Maria Walsh
6/6/2008 01:49:48 PM
CSO
Signed fo Margo Owens

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADM NISTRATION			REQUEST FOR CONSULTATION	
TO *(Division/Office)*: OSE/Division of Risk Management (DRISK)			FROM: Division of Dermatology and Dental Products (DDDP) Contact: Maria Walsh 796-1017	
DATE May 29, 2008	IND NO.	NDA NO 22-129	TYPE OF DOCUMENT New NDA	DATE OF DOCUMENT May 23, 2008
NAME OF DRUG Lice Asphyxiator (benzyl alcohol) 5% (b) (4)	PRIORITY CONSIDERATION		CLASSIFICATION OF DRUG: 1S	DESIRED COMPLETION DATE June 20, 2008
NAME OF FIRM: Summer Laboratories, Inc.				

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE/ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE--NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☐ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER (SPECIFY BELOW):	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE IV STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL-BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

☐ CLINICAL	☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS: **Please review the draft Patient Package Insert (Directions for Use) submitted on 5/23/08 and available in the CDER EDR. Word version requested.**

SIGNATURE OF REQUESTER	METHOD OF DELIVERY (Check one) ☐ MAIL ☐ HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

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/s/

Maria Walsh
5/29/2008 03:45:49 PM

MEMORANDUM OF TELECON

DATE: 12/10/07, 10:30 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, VP 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
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.

The sponsor submitted a list of questions dated December 7, 2007. They are as follows:

The Lice Asphyxiator (LA) formulation was initially studied in (b) (4) Early accelerated stability results indicated weight loss versus time with the (b) (4) container/closure system. The current container/closure system is (b) (4) Polypropylene (PP) and significantly and adequately improved the stability profile for LA. The container, as designed, has a special neck finish and only a few dispensing closures have been identified that will fit this bottle. (b) (4) We have identified a (b) (4) that will fit the current LA bottle. We have also found an orifice reducing plug that will work with the bottle. (b) (4)

We therefore would like additional clarity on the FDA's requirement so that we can move forward efficiently with a plan to address the Agency's desire to readily distinguish LA from an oral liquid product.

1. What are the FDA expectations/requirements regarding timelines for any change to the system?
2. Would a [redacted] (b) (4) allow us to move the requirement out to a post marketing situation?
3. Could we consider the current system with a [redacted] (b) (4). If acceptable, would this require only short term (product use 2 weeks) stability of the new closure?

   The Agency asked the sponsor to clarify what [redacted] (b) (4) looks like.

   [redacted] (b) (4)

   The Agency asked if the pharmacist will attach the [redacted] (b) (4)

   The sponsor responded that they would provide instructions for the end user to attach [redacted] (b) (4)

   The [redacted] (b) (4) would need to be qualified through USP 661 and the sponsor should check to see if the benzyl alcohol is taken up by the closure.

4. Would a conduction seal of [redacted] (b) (4) on the current container allow us to continue to move forward with an alternate [redacted] (b) (4) closure, requiring only short term (product use 2 weeks) stability of the new closure?

   The Agency asked what DMF they are planning to use.

   The sponsor stated that they have identified a DMF but have not tried it on the product yet.

5. Would an orifice reducing plug ([redacted] (b) (4) and current cap be sufficient to differentiate our product from an oral medication? The orifice reducer we have identified [redacted] (b) (4), and is not typically used in oral medication packaging. The orifice reducer would allow us to use the current container closure system. Would any additional information be required with the orifice reducer? Would one stability study, to commence ASAP and then the subsequent additional validation batches be adequate?

   The Agency asked if they can find an orifice reducing plug [redacted] (b) (4).

   The sponsor stated that very few stock the [redacted] (b) (4).

6. Would a new container and closure (b) (4) system of (b) (4) require a restart of the stability clock? Could we commit to this post marketing?

> *The sponsor asked if they could do number 2 and 3 temporarily and then do the stability studies overtime. If they found an off-the-shelf top that fits their bottle, what kind of stability would they need to provide?*

> The Agency stated that it depends on the amount of change in head space and the surface-to-formulation ratio. They must demonstrate compatibility with the formulation and comply with USP 661.

The Agency asked the sponsor to provide an update on where they are with addressing the remaining items in the Information Request Letter.

> *The sponsor responded that they have gone through the Phase 3 study reports and done a careful quality control check. They also had an outside review of the reports conducted and are in the process of finalizing the reports. They have resolved all the issues and it should be completed by the end of next week. The PK study report should be in by the end of next week.*

The Agency responded that they will review the closure options the sponsor presented and get back to them.

The conversation ended amicably.

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/s/

Melinda Bauerlien
5/1/2008 02:03:31 PM
CSO

Jill Lindstrom
5/1/2008 02:45:51 PM
MEDICAL OFFICER

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

FACSIMILE TRANSMITTAL SHEET

DATE: April 30, 2008

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: 2

Comments:
Please send us instructions that were given to subjects in the phase 3 clinical trial today if possible. Also please provide us with a Patient Package Insert.

Document to be mailed: ☐ YES ☑ NO

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If you are not the addressee, or a person authorized to deliver this document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us immediately by telephone at (301) 796-2110. Thank you.

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/s/

Melinda Bauerlien
4/30/2008 10:07:59 AM
CSO

FDA Proposed draft Labeling
NDA 22-129
03/26/09

DRAFT

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

FACSIMILE TRANSMITTAL SHEET

DATE: March 26, 2009

To: Debra Hayes	**From:** Nichelle E. Rashid
Company: Sciele® Pharma, Inc.	Division of Dermatology and Dental Products
Fax number: 678-992-1038	**Fax number:** (301) 796-9895
Phone number: 678-341-1526	**Phone number:** (301) 796-3904

Subject: Draft Labeling for NDA 22-129

Total no. of pages including cover: 11

Comments: Attached is the FDA proposed draft labeling for your NDA 22-129 TRADENAME (benzyl alcohol) Lotion 5%. Please review and provide your written agreement with this proposal or provide your revisions/comments by COB, March 27, 2009. Also, submit your revised "Patient Instruction for Use" Leaflet by COB, March 27, 2009.

Please note the following comments:

1.) **Remove periods of main section numbers. Add a horizontal line at the end of Contents (like the one separating Highlights and Contents).**

2.) **All tables in the label (including Highlights) are hard to read when printed. Re-do all tables.**

3.) **TABLE 4: In first column, replace** (b) (4) **with "free" so that table contents are consistent with title.**

Document to be mailed: ☐ YES ☑ NO

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If you are not the addressee, or a person authorized to deliver this document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us immediately by telephone at (301) 796-2110. Thank you.

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/s/

Nichelle Rashid
3/26/2009 02:29:09 PM
CSO

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Office/Division)*: OND/Pediatric and Maternal Health Staff
Attention: Rosemary Addy

FROM (*Name, Office/Division, and Phone Number of Requestor)*:
Nichelle Rashid/OND/DDDP (301) 796-3904
Gordana Diglisic, Clinical Reviewer, (301) 796-2271
Jill Lindstrom, Clinical Team Leader, (301) 796-0944

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
02/18/09		22-129	Labeling (PI)	

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
TRADENAME (benzyl alcohol) Lotion, 5%			02/24/09

NAME OF FIRM: Sciele Pharma, Inc.

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END-OF-PHASE 2a MEETING
- ☐ END-OF-PHASE 2 MEETING
- ☐ RESUBMISSION
- ☐ SAFETY / EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☒ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☐ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

- ☐ PRIORITY P NDA REVIEW
- ☐ END-OF-PHASE 2 MEETING
- ☐ CONTROLLED STUDIES
- ☐ PROTOCOL REVIEW
- ☐ OTHER (SPECIFY BELOW):
- ☐ CHEMISTRY REVIEW
- ☐ PHARMACOLOGY
- ☐ BIOPHARMACEUTICS
- ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE 4 STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL - BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG SAFETY

- ☐ PHASE 4 SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE, e.g., POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ NONCLINICAL

COMMENTS / SPECIAL INSTRUCTIONS: Please review the proposed revised labeling from the applicant. Please weigh in on the need for a contraindication in preterm neonates and a statement in the warnings and precaution and pediatric use sections related to use under 6 months of age.

SIGNATURE OF REQUESTOR
Nichelle Rashid

METHOD OF DELIVERY (Check one)
☒ DFS ☐ EMAIL ☐ MAIL ☐ HAND

PRINTED NAME AND SIGNATURE OF RECEIVER

PRINTED NAME AND SIGNATURE OF DELIVERER

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/s/

Nichelle Rashid
3/17/2009 04:55:28 PM

MEMORANDUM OF MINUTES OF PRE-APPROVAL SAFETY CONFERENCE

MEETING DATE: March 3, 2009
TIME: 10:00 AM (EDT)
LOCATION: WO, Bld. 22, room 4270
APPLICATION: NDA 22-129
DRUG NAME: TRADENAME (benzyl alcohol) 5% Lotion
TYPE OF MEETING: Pre-Approval Safety Conference

MEETING CHAIR: Jill Lindstrom, M.D.

MEETING RECORDER: J. Paul Phillips

FDA ATTENDEES:

Julie Beitz, M.D., Director, ODE III
Susan Walker, M.D., Director, DDDP
Tatiana Oussova, M.D., M.P.H., Deputy Director of Safety, DDDP
Jill Lindstrom, M.D., Clinical Team Leader & CDTL, DDDP
Gordana Diglisic, M.D., Clinical Reviewer, DDDP
Barbara Hill, Ph.D., Pharmacology Team Leader, DDDP
Shulin Ding, Ph.D., Pharmaceutical Assessment Lead, DPMA II, Branch III
Tarun Mehta, M.Sc., Product Quality Reviewer, DPMA II, Branch III
Mohamed Al-Osh, Ph.D., Biostatistics Team Leader, DB III
Abimbola Adebowale, Ph.D., Clinical Pharmacology Reviewer, DCP III
Ida-Lina Diak, Pharm.D., Safety Evaluator TL (acting), DPV I
Namita Kothary, Pharm.D., Safety Evaluator, DPV I
Loretta Holmes, B.S.N., Pharm.D., Safety Evaluator, DMEPA
Nancy Carothers, R.N., B.A., Patient Labeling Reviewer, DRISK
Margo Owens, Project Management Team Leader, DDDP
J. Paul Phillips, M.S., Regulatory Health Project Manager, DDDP
Sue Kang, B.S., Regulatory Health Project Manager, DDDP
Catherine Carr, M.S., Regulatory Health Project Manager, DDDP
Lt. Dawn Williams, R.N., B.S.N., U.S.P.H.S., Regulatory Health Project Manager, DDDP
Kelisha C. Turner, Regulatory Health Project Manager, DDDP

BACKGROUND:

Sciele Pharma, Inc. submitted their New Drug Application (NDA) on June 15, 2007 as a 505(b)(2) application for TRADENAME (benzyl alcohol) Lotion, 5% for topical treatment of head lice infestation in patients 6 months of age and older.

The sponsor submitted a complete response to the July 14, 2008 approvable action letter on October 17, 2008.

DISCUSSION POINTS:

OSE recommended active monitoring of AERS for signals with specific focus on the following:

- Infant Gasping Syndrome
- Medication errors (i.e.,: ingestion)
- Ocular exposure

The Division concurs with OSE's recommendation.

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 /s/
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Jill Lindstrom
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MEMORANDUM OF TELECON

Date: February 6, 2009

Time: 2:00 p.m.

Application: NDA 22-129, Tradename (benzyl alcohol) 5% lotion

Meeting Chair: Shulin Ding, Ph.D., Pharmaceutical Assessment Lead, ONDQA

Meeting Recorder: Nichelle Rashid, Regulatory Project Manager

FDA Participants:

Gordana Diglisic M.D., Clinical Reviewer, DDDP
Shulin Ding, Ph.D., Pharmaceutical Assessment Lead, ONDQA
Tarun Mehta, Ph.D., Chemistry Reviewer, ONDQA
Nichelle Rashid, Regulatory Project Manager, DDDP
Jeannie David, Regulatory Project Manager, ONDQA

Applicant:

Sciele Pharma, Inc.
Debra Hayes, Regulatory Affairs Manager, Sciele
Larry Dillaha, MD, EVP and Chief Medical Officer, Sciele
Mike Precopio, President, Summers Laboratories
John Colyar, VP Manufacturing and Development

Background:

Sciele Pharma, Inc. submitted a complete response to the Approvable Letter issued on October 17, 2008 for NDA 22-129, Tradename (benzyl alcohol) 5% lotion. CMC requested a telecon with the applicant to convey CMC specific issues.

Telecon Minutes:

The Agency requested that the applicant amend the NDA by committing to the following:

- In accordance with 21 CFR 314.81 (b)(1)(ii), any change or deterioration in the drug product will be reported to FDA.

  The applicant agreed.

- Any batches not meeting regulatory specifications for the drug product will be withdrawn from the commercial distribution and FDA will be notified via a field alert report in accordance with 21 CFR 314.81 (b)(1)(ii).

  The applicant agreed.

- Please commit to perform the full-scale ICH stability studies on the first three commercial batches to support the switch to the natural bottles.

  The applicant agreed.

- The Agency requested that the applicant submit their amendment to the NDA no later than February 12, 2009.

  The applicant agreed.

The discussion ended amicably.

ADDENDUM

The applicant submitted an amendment to the pending application with the agreed upon changes on February 10, 2009.

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/s/

Nichelle Rashid
2/27/2009 02:16:57 PM
CSO

Shulin Ding
3/3/2009 02:31:12 PM
CHEMIST