

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**22-563**

**ADMINISTRATIVE and CORRESPONDENCE**  
**DOCUMENTS**

## EXCLUSIVITY SUMMARY

NDA # 022563

SUPPL # N/A

HFD # 540

Trade Name SORILUX™

Generic Name calcipotriene

Applicant Name Stiefel Laboratories, Inc.

Approval Date, If Known

### **PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?**

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES  NO

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3, SE4, SE5, SE6, SE7, SE8

505(b)(2)

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES  NO

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?

YES  NO

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

Three years

e) Has pediatric exclusivity been granted for this Active Moiety?

YES  NO

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES  NO

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

## **PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES**

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES  NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# 020273	Dovonex (calcipotriene) Topical Ointment, 0.005%
NDA# 020554	Dovonex (calcipotriene) Topical Cream, 0.005%
NDA# 020611	Dovonex (calcipotriene) Topical Solution, 0.005%
021852	Taclonex (betamethasone dipropionate 0.064% and calcipotriene hydrate, 0.005%) Topical Ointment
022185	Taclonex (betamethasone dipropionate 0.064% and calcipotriene hydrate 0.005%) Topical Suspension

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES  NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#

NDA#

NDA#

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. (Caution: The questions in part II of the summary should only be answered "NO" for original approvals of new molecular entities.)

IF "YES," GO TO PART III.

**PART III THREE-YEAR EXCLUSIVITY FOR NDAs AND SUPPLEMENTS**

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical

investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES  NO

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES  NO

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES  NO

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES  NO

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently

demonstrate the safety and effectiveness of this drug product?

YES  NO

If yes, explain:

- (c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

-U0267-301 and U0267-302

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

- a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES  NO

Investigation #2 YES  NO

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

- b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES  NO

Investigation #2

YES

NO

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

-U0267-301 and U0267-302

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1  
IND # 071198      YES       !  
!      ! NO   
! Explain:

Investigation #2  
IND # 071198      YES       !  
!      ! NO   
! Explain:

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in

interest provided substantial support for the study?

Investigation #1  
!  
!  
YES  ! NO   
Explain: ! Explain:

Investigation #2  
!  
!  
YES  ! NO   
Explain: ! Explain:

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES  NO

If yes, explain:

=====

Name of person completing form: Jeannine M. Helm  
Title: Regulatory Project Manager  
Date: September 10, 2010

Name of Office/Division Director signing form: Susan J. Walker, M. D.  
Title: Division Director, DDDP

Form OGD-011347; Revised 05/10/2004; formatted 2/15/05

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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JEANNINE M HELM  
10/06/2010

SUSAN J WALKER  
10/06/2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		REQUEST FOR CONSULTATION		
TO ( <i>Division/Office</i> ): Barbara Gould, Chief, Project Management Staff Margo Owens, Chief, Project Management Staff Division of Dermatologic and Dental Products		FROM( <i>Division/Office</i> ): Sheetal Patel, PharmD, Lynn Panholzer, PharmD Regulatory Review Officers, Division of Drug Marketing, Advertising and Communication, WO 51 RM 3226/ RM 3372		
DATE: 11/04/10	IND NO.	NDA NO. 022563	TYPE OF DOCUMENT: Patient Brochure/Sales Aid	DATE OF DOCUMENTS:
NAME OF DRUG Sorilux™ (calcipotriene) Foam, 0.005%	PRIORITY CONSIDERATION YES-launch	CLASSIFICATION OF DRUG:	DESIRED COMPLETION DATE: 11/23/10	
NAME OF FIRM: Stiefel Laboratories, Inc.				
<b>REASON FOR REQUEST</b>				
<b>I. GENERAL</b>				
<input type="checkbox"/> NEW PROTOCOL <input type="checkbox"/> PROGRESS REPORT <input type="checkbox"/> NEW CORRESPONDENCE <input checked="" type="checkbox"/> DRUG ADVERTISING <input type="checkbox"/> ADVERSE REACTION <input type="checkbox"/> REPORT <input type="checkbox"/> MANUFACTURING <input type="checkbox"/> CHANGE/ADDITIO <input type="checkbox"/> MEETING PLANNED BY <input type="checkbox"/> PRE--NDA MEETING <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> SAFETY <input type="checkbox"/> PAPER NDA <input type="checkbox"/> CONTROL SUPPLEMENT <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER <input type="checkbox"/> FINAL PRINTED LABELING <input type="checkbox"/> LABELING REVISION <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE <input type="checkbox"/> FORMULATIVE REVIEW <input type="checkbox"/> OTHER ( <i>SPECIFY BELOW</i> ):				
<b>COMMENTS/SPECIAL INSTRUCTIONS:</b>				
DDMAC is reviewing a proposed launch patient brochure and sales aid for Sorilux for advisory comments. Please see attached questions in regards to this submission. The questions are outlined below, and we welcome any additional input on the proposed patient brochure and sales aid. If you have any questions, Sheetal Patel may be reached at (301)796-5167 and Lynn Panholzer at (301) 796-0616.				
SIGNATURE OF REQUESTER		METHOD OF DELIVERY (Check one) <input checked="" type="checkbox"/> DARRTS (references will be hand-delivered)		
SIGNATURE OF RECEIVER		SIGNATURE OF DELIVERER		

**MEMORANDUM**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communication

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Date: Nov. 04, 2010  
From: Sheetal Patel, PharmD; Lynn Panholzer, PharmD  
Regulatory Review Officers, DDMAC  
To: Barbara Gould, Chief, Project Management Staff  
Margo Owens, Chief, Project Management Staff  
Division of Dermatologic and Dental Products  
Re: Consult for DDMAC on Sorilux™ (calcipotriene) Foam, 0.005%  
Patient brochure and sales aid  
NDA: 022563

DDMAC is reviewing a proposed launch patient brochure and sales aid for Sorilux for advisory comments. Please see attached questions in regards to this submission. The questions are outlined below, and we welcome any additional input on the proposed patient brochure and sales aid. If you have any questions, Sheetal Patel may be reached at (301)796-5167 and Lynn Panholzer at (301) 796-0616.

**Patient Brochure**



1 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

(b) (4)

[Redacted text block]

28 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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SHEETAL PATEL  
11/04/2010

# ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION <sup>1</sup>		
NDA # 022563 BLA # N/A	NDA Supplement # N/A BLA STN # N/A	If NDA, Efficacy Supplement Type: N/A
Proprietary Name: Sorilux Established/Proper Name: calcipotriene Dosage Form: Foam, 0.005%		Applicant: Stiefel Laboratories, Inc. Agent for Applicant (if applicable): N/A
RPM: Jeannine M. Helm		Division: Dermatology and Dental Products
<p><u>NDA's:</u> NDA Application Type: <input type="checkbox"/> 505(b)(1) <input checked="" type="checkbox"/> 505(b)(2) Efficacy Supplement: <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)</p> <p>(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). Consult page 1 of the NDA Regulatory Filing Review for this application or Appendix A to this Action Package Checklist.)</p>		<p><u>505(b)(2) Original NDAs and 505(b)(2) NDA supplements:</u> Listed drug(s) referred to in 505(b)(2) application (include NDA/ANDA #s) and drug name(s):</p> <p>Dovonex (calcipotriene) Ointment, 0.005% -NDA 020273, Leo Pharma</p> <p>Provide a brief explanation of how this product is different from the listed drug.</p> <p>Different Dosage Form</p> <p><input type="checkbox"/> If no listed drug, check here and explain:</p> <p><b>Prior to approval, review and confirm the information previously provided in Appendix B to the Regulatory Filing Review by re-checking the Orange Book for any new patents and pediatric exclusivity. If there are any changes in patents or exclusivity, notify the OND ADRA immediately and complete a new Appendix B of the Regulatory Filing Review.</b></p> <p style="text-align: center;"><input checked="" type="checkbox"/> No changes      <input type="checkbox"/> Updated Date of check: 10.5.2010</p> <p><b>If pediatric exclusivity has been granted or the pediatric information in the labeling of the listed drug changed, determine whether pediatric information needs to be added to or deleted from the labeling of this drug.</b></p> <p><b><u>On the day of approval</u>, check the Orange Book again for any new patents or pediatric exclusivity.</b></p>
❖ Actions		
<ul style="list-style-type: none"> <li>• Proposed action</li> <li>• User Fee Goal Date is <u>October 21, 2010</u></li> </ul>		<input checked="" type="checkbox"/> AP <input type="checkbox"/> TA <input type="checkbox"/> CR
<ul style="list-style-type: none"> <li>• Previous actions (<i>specify type and date for each action taken</i>)</li> </ul>		<input checked="" type="checkbox"/> None

<sup>1</sup> The **Application Information** section is (only) a checklist. The **Contents of Action Package** section (beginning on page 5) lists the documents to be included in the Action Package.

<p>❖ If accelerated approval, were promotional materials received? Note: For accelerated approval (21 CFR 314.510/601.41), promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see <a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf</a>). If not submitted, explain _____</p>	<input type="checkbox"/> Received
<p>❖ Application Characteristics<sup>2</sup></p>	
<p>Review priority: <input checked="" type="checkbox"/> Standard <input type="checkbox"/> Priority Chemical classification (new NDAs only):</p> <p><input type="checkbox"/> Fast Track <input type="checkbox"/> Rx-to-OTC full switch  <input type="checkbox"/> Rolling Review <input type="checkbox"/> Rx-to-OTC partial switch  <input type="checkbox"/> Orphan drug designation <input type="checkbox"/> Direct-to-OTC</p> <p>NDAs: Subpart H <span style="margin-left: 200px;">BLAs: Subpart E</span>  <input type="checkbox"/> Accelerated approval (21 CFR 314.510) <span style="margin-left: 100px;"><input type="checkbox"/> Accelerated approval (21 CFR 601.41)</span>  <input type="checkbox"/> Restricted distribution (21 CFR 314.520) <span style="margin-left: 100px;"><input type="checkbox"/> Restricted distribution (21 CFR 601.42)</span>          Subpart I <span style="margin-left: 200px;">Subpart H</span>  <input type="checkbox"/> Approval based on animal studies <span style="margin-left: 100px;"><input type="checkbox"/> Approval based on animal studies</span></p> <p><input type="checkbox"/> Submitted in response to a PMR  <input type="checkbox"/> Submitted in response to a PMC  <input type="checkbox"/> Submitted in response to a Pediatric Written Request</p> <p>Comments:</p>	
<p>❖ BLAs only: <i>RMS-BLA Product Information Sheet for TBP</i> has been completed and forwarded to OBPS/DRM (<i>approvals only</i>)</p>	<input type="checkbox"/> Yes, date
<p>❖ BLAs only: is the product subject to official FDA lot release per 21 CFR 610.2 (<i>approvals only</i>)</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>❖ Public communications (<i>approvals only</i>)</p>	
<ul style="list-style-type: none"> <li>• Office of Executive Programs (OEP) liaison has been notified of action</li> </ul>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<ul style="list-style-type: none"> <li>• Press Office notified of action (by OEP)</li> </ul>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> <li>• Indicate what types (if any) of information dissemination are anticipated</li> </ul>	<input checked="" type="checkbox"/> None <input type="checkbox"/> HHS Press Release <input type="checkbox"/> FDA Talk Paper <input type="checkbox"/> CDER Q&As <input type="checkbox"/> Other

<sup>2</sup> Answer all questions in all sections in relation to the pending application, i.e., if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA. For example, if the application is a pending BLA supplement, then a new *RMS-BLA Product Information Sheet for TBP* must be completed.

❖ Exclusivity	
<ul style="list-style-type: none"> <li>Is approval of this application blocked by any type of exclusivity?</li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
<ul style="list-style-type: none"> <li>NDA and BLAs: Is there existing orphan drug exclusivity for the “same” drug or biologic for the proposed indication(s)? <i>Refer to 21 CFR 316.3(b)(13) for the definition of “same drug” for an orphan drug (i.e., active moiety). This definition is NOT the same as that used for NDA chemical classification.</i></li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If, yes, NDA/BLA #      and date exclusivity expires:
<ul style="list-style-type: none"> <li>(b)(2) NDAs only: Is there remaining 5-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i></li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA #      and date exclusivity expires:
<ul style="list-style-type: none"> <li>(b)(2) NDAs only: Is there remaining 3-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i></li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA #      and date exclusivity expires:
<ul style="list-style-type: none"> <li>(b)(2) NDAs only: Is there remaining 6-month pediatric exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i></li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA #      and date exclusivity expires:
<ul style="list-style-type: none"> <li>NDAs only: Is this a single enantiomer that falls under the 10-year approval limitation of 505(u)? <i>(Note that, even if the 10-year approval limitation period has not expired, the application may be tentatively approved if it is otherwise ready for approval.)</i></li> </ul>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA #      and date 10-year limitation expires:
❖ Patent Information (NDAs only)	
<ul style="list-style-type: none"> <li>Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought. If the drug is an old antibiotic, skip the Patent Certification questions.</li> </ul>	<input checked="" type="checkbox"/> Verified <input type="checkbox"/> Not applicable because drug is an old antibiotic.
<ul style="list-style-type: none"> <li>Patent Certification [505(b)(2) applications]: Verify that a certification was submitted for each patent for the listed drug(s) in the Orange Book and identify the type of certification submitted for each patent.</li> </ul>	21 CFR 314.50(i)(1)(i)(A) <input type="checkbox"/> Verified 21 CFR 314.50(i)(1) <input checked="" type="checkbox"/> (ii) <input type="checkbox"/> (iii)
<ul style="list-style-type: none"> <li>[505(b)(2) applications] If the application includes a <b>paragraph III</b> certification, it cannot be approved until the date that the patent to which the certification pertains expires (but may be tentatively approved if it is otherwise ready for approval).</li> </ul>	<input checked="" type="checkbox"/> No paragraph III certification Date patent will expire
<ul style="list-style-type: none"> <li>[505(b)(2) applications] For <b>each paragraph IV</b> certification, verify that the applicant notified the NDA holder and patent owner(s) of its certification that the patent(s) is invalid, unenforceable, or will not be infringed (review documentation of notification by applicant and documentation of receipt of notice by patent owner and NDA holder). <i>(If the application does not include any paragraph IV certifications, mark “N/A” and skip to the next section below (Summary Reviews)).</i></li> </ul>	<input checked="" type="checkbox"/> N/A (no paragraph IV certification) <input type="checkbox"/> Verified

- [505(b)(2) applications] For **each paragraph IV** certification, based on the questions below, determine whether a 30-month stay of approval is in effect due to patent infringement litigation.

Answer the following questions for **each** paragraph IV certification:

- (1) Have 45 days passed since the patent owner's receipt of the applicant's notice of certification?

Yes     No

(Note: The date that the patent owner received the applicant's notice of certification can be determined by checking the application. The applicant is required to amend its 505(b)(2) application to include documentation of this date (e.g., copy of return receipt or letter from recipient acknowledging its receipt of the notice) (see 21 CFR 314.52(e)).

If "**Yes**," skip to question (4) below. If "**No**," continue with question (2).

- (2) Has the patent owner (or NDA holder, if it is an exclusive patent licensee) submitted a written waiver of its right to file a legal action for patent infringement after receiving the applicant's notice of certification, as provided for by 21 CFR 314.107(f)(3)?

Yes     No

If "**Yes**," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip the rest of the patent questions.

If "**No**," continue with question (3).

- (3) Has the patent owner, its representative, or the exclusive patent licensee filed a lawsuit for patent infringement against the applicant?

Yes     No

(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)).

If "**No**," the patent owner (or NDA holder, if it is an exclusive patent licensee) has until the expiration of the 45-day period described in question (1) to waive its right to bring a patent infringement action or to bring such an action. After the 45-day period expires, continue with question (4) below.

- (4) Did the patent owner (or NDA holder, if it is an exclusive patent licensee) submit a written waiver of its right to file a legal action for patent infringement within the 45-day period described in question (1), as provided for by 21 CFR 314.107(f)(3)?

Yes     No

If "**Yes**," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (Summary Reviews).

If "**No**," continue with question (5).

<p>(5) Did the patent owner, its representative, or the exclusive patent licensee bring suit against the (b)(2) applicant for patent infringement within 45 days of the patent owner's receipt of the applicant's notice of certification?</p> <p>(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)). If no written notice appears in the NDA file, confirm with the applicant whether a lawsuit was commenced within the 45-day period).</p> <p><i>If "No," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (Summary Reviews).</i></p> <p><i>If "Yes," a stay of approval may be in effect. To determine if a 30-month stay is in effect, consult with the OND ADRA and attach a summary of the response.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
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**CONTENTS OF ACTION PACKAGE**

❖ Copy of this Action Package Checklist <sup>3</sup>	October 8, 2010
<b>Officer/Employee List</b>	
❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list ( <i>approvals only</i> )	<input checked="" type="checkbox"/> Included
Documentation of consent/non-consent by officers/employees	<input checked="" type="checkbox"/> Included
<b>Action Letters</b>	
❖ Copies of all action letters ( <i>including approval letter with final labeling</i> )	Action(s) and date(s) Approval: 10.6.2010
<b>Labeling</b>	
❖ Package Insert ( <i>write submission/communication date at upper right of first page of PI</i> )	
<ul style="list-style-type: none"> <li>• Most recent draft labeling. If it is division-proposed labeling, it should be in track-changes format.</li> </ul>	10.5.2010
<ul style="list-style-type: none"> <li>• Original applicant-proposed labeling</li> </ul>	12.19.2009
<ul style="list-style-type: none"> <li>• Example of class labeling, if applicable</li> </ul>	

<sup>3</sup> Fill in blanks with dates of reviews, letters, etc.  
Version: 12/4/09

❖ Medication Guide/Patient Package Insert/Instructions for Use ( <i>write submission/communication date at upper right of first page of each piece</i> )	<input type="checkbox"/> Medication Guide <input checked="" type="checkbox"/> Patient Package Insert <input type="checkbox"/> Instructions for Use <input type="checkbox"/> None
<ul style="list-style-type: none"> <li>Most-recent draft labeling. If it is division-proposed labeling, it should be in track-changes format.</li> </ul>	10.1.2010
<ul style="list-style-type: none"> <li>Original applicant-proposed labeling</li> </ul>	12.19.2009
<ul style="list-style-type: none"> <li>Example of class labeling, if applicable</li> </ul>	
❖ Labels ( <b>full color</b> carton and immediate-container labels) ( <i>write submission/communication date on upper right of first page of each submission</i> )	
<ul style="list-style-type: none"> <li>Most-recent draft labeling</li> </ul>	9.10.2010
❖ Proprietary Name <ul style="list-style-type: none"> <li>Acceptability/non-acceptability letter(s) (<i>indicate date(s)</i>)</li> <li>Review(s) (<i>indicate date(s)</i>)</li> </ul>	Proprietary Name Review: 9.22.2010 Conditionally Acceptable: 4.16.2010 OSE Proprietary Name Review: 9.15. 2010
❖ Labeling reviews ( <i>indicate dates of reviews and meetings</i> )	<input checked="" type="checkbox"/> RPM 3.23.2010 <input checked="" type="checkbox"/> DMEDP 8.4.2010 <input checked="" type="checkbox"/> DRISK 8.16.2010 <input checked="" type="checkbox"/> DDMAC 8.20.2010 <input type="checkbox"/> CSS <input checked="" type="checkbox"/> Other reviews OSE/DPV: 6.1.2010 SEALD: 10.6.2010
<b>Administrative / Regulatory Documents</b>	
❖ Administrative Reviews ( <i>e.g., RPM Filing Review<sup>4</sup>/Memo of Filing Meeting</i> ) ( <i>indicate date of each review</i> )	505(b)(2) Assessment: 9.15.2010 RPM Filing Review: 6.4.2010
❖ NDAs only: Exclusivity Summary ( <i>signed by Division Director</i> )	<input checked="" type="checkbox"/> Included
❖ Application Integrity Policy (AIP) Status and Related Documents <a href="http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm">http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm</a>	
<ul style="list-style-type: none"> <li>Applicant in on the AIP</li> </ul>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> <li>This application is on the AIP <ul style="list-style-type: none"> <li>If yes, Center Director's Exception for Review memo (<i>indicate date</i>)</li> <li>If yes, OC clearance for approval (<i>indicate date of clearance communication</i>)</li> </ul> </li> </ul>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  <input type="checkbox"/> Not an AP action
❖ Pediatrics ( <i>approvals only</i> ) <ul style="list-style-type: none"> <li>Date reviewed by PeRC <u>7.21.2010</u> If PeRC review not necessary, explain: _____</li> <li>Pediatric Page (<i>approvals only, must be reviewed by PERC before finalized</i>)</li> </ul>	<input checked="" type="checkbox"/> Included
❖ Debarment certification (original applications only): verified that qualifying language was not used in certification and that certifications from foreign applicants are cosigned by U.S. agent ( <i>include certification</i> )	<input checked="" type="checkbox"/> Verified, statement is acceptable

<sup>4</sup> Filing reviews for scientific disciplines should be filed behind the respective discipline tab.

❖ Outgoing communications ( <i>letters (except action letters), emails, faxes, telecons</i> )	Included
❖ Internal memoranda, telecons, etc.	N/A
❖ Minutes of Meetings	
<ul style="list-style-type: none"> <li>• Pre-Approval Safety Conference (<i>indicate date of mtg; approvals only</i>)</li> </ul>	Not applicable (Non-NME)
<ul style="list-style-type: none"> <li>• Regulatory Briefing (<i>indicate date of mtg</i>)</li> </ul>	<input checked="" type="checkbox"/> No mtg
<ul style="list-style-type: none"> <li>• If not the first review cycle, any end-of-review meeting (<i>indicate date of mtg</i>)</li> </ul>	<input checked="" type="checkbox"/> N/A or no mtg
<ul style="list-style-type: none"> <li>• Pre-NDA/BLA meeting (<i>indicate date of mtg</i>)</li> </ul>	<input type="checkbox"/> No mtg 10.30.2009
<ul style="list-style-type: none"> <li>• EOP2 meeting (<i>indicate date of mtg</i>)</li> </ul>	<input type="checkbox"/> No mtg 10.24.2007
<ul style="list-style-type: none"> <li>• Other milestone meetings (e.g., EOP2a, CMC pilot programs) (<i>indicates dates</i>)</li> </ul>	N/A
❖ Advisory Committee Meeting(s)	<input checked="" type="checkbox"/> No AC meeting
<ul style="list-style-type: none"> <li>• Date(s) of Meeting(s)</li> </ul>	
<ul style="list-style-type: none"> <li>• 48-hour alert or minutes, if available (<i>do not include transcript</i>)</li> </ul>	
<b>Decisional and Summary Memos</b>	
❖ Office Director Decisional Memo ( <i>indicate date for each review</i> )	<input checked="" type="checkbox"/> None
Division Director Summary Review ( <i>indicate date for each review</i> )	<input type="checkbox"/> None 10.6.2010
Cross-Discipline Team Leader Review ( <i>indicate date for each review</i> )	<input type="checkbox"/> None 9.24.2010
PMR/PMC Development Templates ( <i>indicate total number</i> )	<input type="checkbox"/> None 3
<b>Clinical Information<sup>5</sup></b>	
❖ Clinical Reviews	
<ul style="list-style-type: none"> <li>• Clinical Team Leader Review(s) (<i>indicate date for each review</i>)</li> </ul>	See CDTL Review.
<ul style="list-style-type: none"> <li>• Clinical review(s) (<i>indicate date for each review</i>)</li> </ul>	Clinical Review: 9.17.2010; Memo to File- Review of Response to 74 day Letter: 3.14.2010 Filing Review: 2.5.2010
<ul style="list-style-type: none"> <li>• Social scientist review(s) (if OTC drug) (<i>indicate date for each review</i>)</li> </ul>	<input checked="" type="checkbox"/> None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here <input type="checkbox"/> and include a review/memo explaining why not ( <i>indicate date of review/memo</i> )	Clinical Review: 9.17.2010- pg. 19
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers ( <i>indicate date of each review</i> )	<input type="checkbox"/> None PMHS: 5.27.2010
❖ Controlled Substance Staff review(s) and Scheduling Recommendation ( <i>indicate date of each review</i> )	<input checked="" type="checkbox"/> Not applicable
❖ Risk Management <ul style="list-style-type: none"> <li>• REMS Document and Supporting Statement (<i>indicate date(s) of submission(s)</i>)</li> <li>• REMS Memo (<i>indicate date</i>)</li> <li>• Risk management review(s) and recommendations (including those by OSE and CSS) (<i>indicate date of each review and indicate location/date if incorporated into another review</i>)</li> </ul>	<input checked="" type="checkbox"/> None

<sup>5</sup> Filing reviews should be filed with the discipline reviews.

❖ DSI Clinical Inspection Review Summary(ies) (include copies of DSI letters to investigators)	<input type="checkbox"/> None requested Summary Review: 8.18.2010 Letters to Investigators: 8.18.2010; 8.10.2010; 6.21.2010;
<b>Clinical Microbiology</b> <input checked="" type="checkbox"/> None	
❖ Clinical Microbiology Team Leader Review(s) (indicate date for each review)	<input type="checkbox"/> None
Clinical Microbiology Review(s) (indicate date for each review)	<input type="checkbox"/> None
<b>Biostatistics</b> <input type="checkbox"/> None	
❖ Statistical Division Director Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
Statistical Team Leader Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
Statistical Review(s) (indicate date for each review)	<input type="checkbox"/> None Biostatistics Review: 8.26.2010; Filing Review: 2.19.2010
<b>Clinical Pharmacology</b> <input type="checkbox"/> None	
❖ Clinical Pharmacology Division Director Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
Clinical Pharmacology Team Leader Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
Clinical Pharmacology review(s) (indicate date for each review)	<input type="checkbox"/> None Clinical Pharmacology Review: 8.26.2010; Filing Review: 2.12.2010
❖ DSI Clinical Pharmacology Inspection Review Summary (include copies of DSI letters)	<input checked="" type="checkbox"/> None
<b>Nonclinical</b> <input type="checkbox"/> None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
• Supervisory Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
• Pharm/tox review(s), including referenced IND reviews (indicate date for each review)	<input type="checkbox"/> None Pharm/Tox Review: 8.25.2010; Filing Review: 2.17.2010
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer (indicate date for each review)	<input checked="" type="checkbox"/> None
❖ Statistical review(s) of carcinogenicity studies (indicate date for each review)	<input checked="" type="checkbox"/> No carc
❖ ECAC/CAC report/memo of meeting	<input checked="" type="checkbox"/> None Included in P/T review, page
❖ DSI Nonclinical Inspection Review Summary (include copies of DSI letters)	<input checked="" type="checkbox"/> None requested
<b>Product Quality</b> <input type="checkbox"/> None	
❖ Product Quality Discipline Reviews	
• ONDQA/OBP Division Director Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
• Branch Chief/Team Leader Review(s) (indicate date for each review)	<input checked="" type="checkbox"/> None
• Product quality review(s) including ONDQA biopharmaceutics reviews (indicate date for each review)	<input type="checkbox"/> None Product Quality Review: 9.7.2010; Filing Review: 2.16.2010

<p>❖ Microbiology Reviews</p> <p><input checked="" type="checkbox"/> NDAs: Microbiology reviews (sterility &amp; pyrogenicity) (OPS/NDMS) (<i>indicate date of each review</i>)</p> <p><input type="checkbox"/> BLAs: Sterility assurance, microbiology, facilities reviews (DMPQ/MAPCB/BMT) (<i>indicate date of each review</i>)</p>	<p><input type="checkbox"/> Not needed</p> <p>Product Quality Microbiology Review: 8.27.2010</p>
<p>❖ Reviews by other disciplines/divisions/Centers requested by CMC/quality reviewer (<i>indicate date of each review</i>)</p>	<p><input checked="" type="checkbox"/> None</p>
<p>❖ Environmental Assessment (check one) (original and supplemental applications)</p>	
<p><input checked="" type="checkbox"/> Categorical Exclusion (<i>indicate review date</i>)(<i>all original applications and all efficacy supplements that could increase the patient population</i>)</p>	<p>Product Quality Review: 9.7.2010; page 7</p>
<p><input type="checkbox"/> Review &amp; FONSI (<i>indicate date of review</i>)</p>	<p>N/A</p>
<p><input checked="" type="checkbox"/> Review &amp; Environmental Impact Statement (<i>indicate date of each review</i>)</p>	<p>Product Quality Review: 9.7.2010; page 61</p>
<p>❖ Facilities Review/Inspection</p>	
<p><input checked="" type="checkbox"/> NDAs: Facilities inspections (include EER printout) (<i>date completed must be within 2 years of action date</i>)</p>	<p>Date completed: Product Quality Review: 9.7.2010, pages 64-67. <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation</p>
<p><input type="checkbox"/> BLAs: TB-EER (<i>date of most recent TB-EER must be within 30 days of action date</i>)</p>	<p>Date completed: <input type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation</p>
<p>❖ NDAs: Methods Validation (<i>check box only, do not include documents</i>)</p>	<p><input type="checkbox"/> Completed <input type="checkbox"/> Requested <input type="checkbox"/> Not yet requested <input checked="" type="checkbox"/> Not needed</p>

## Appendix A to Action Package Checklist

An NDA or NDA supplemental 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) **Or** 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.
- (3) **Or** 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) **And** 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.
- (3) **And** 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) **Or** 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.
- (3) **Or** 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 ADRA.

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/s/

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JEANNINE M HELM  
10/08/2010

## MEMORANDUM OF TELECONFERENCE MINUTES

**TCON DATE:** September 28, 2010  
**APPLICATION:** NDA 022563  
**DRUG NAME:** Sorilux (calcipotriene) Foam, 0.005%  
**SPONSOR:** Stiefel Laboratories, Inc.

**TYPE OF MEETING:** Notification of Pediatric Research Equity Act (PREA)  
Postmarketing Requirements (PMRs) for NDA 022563 Sorilux  
(calcipotriene) Foam, 0.005%, and Proposed Timelines Request for  
PREA PMR

**MEETING CHAIR:** Melinda McCord, M.D., Clinical Reviewer, DDDP

**MEETING RECORDER:** Jeannine Helm, Regulatory Health Project Manager, DDDP

### **FDA ATTENDEES:**

Tatiana Oussova, M.D., M.P.H., Deputy Director of Safety, DDDP  
Jill Lindstrom, M.D., Clinical Team Leader, DDDP  
Melinda McCord, M.D., Clinical Reviewer, DDDP  
Barbara Gould, M.B.A.H.C.M., Chief, Project Management Staff, DDDP  
Margo Owens, Project Management Team Leader, DDDP  
Jeannine Helm, Regulatory Health Project Manager, DDDP

### **SPONSOR ATTENDEES:**

Salisa A. Hauptmann, MPH, Vice President, Global Regulatory Affairs and R&D Quality  
Melody Wyres, MS, Director, Clinical Development  
Tom Brundage, MS, Director, Data Sciences  
Emilio Arbe, MD, Senior Director, Clinical Research  
Jeff Troughton, MS, RAC, Associate Director, Regulatory Affairs

### **DISCUSSION POINTS:**

1. The Agency notified the sponsor that PREA PMRs will be required for NDA 022563 Sorilux (calcipotriene) Foam, 0.005%.
2. The Agency further stated that we will be requesting a proposed timelines for these PREA PMRs. The requested response date will be September 30, 2010.
3. The sponsor asked whether further action would be necessary if the Agency accepted the proposed PREA PMR timelines. The Agency responded that no other actions would be required at this time. The Agency reminded the sponsor to formally submit the response to the NDA.

**ACTION ITEMS:**

- The Agency will send the sponsor electronically a request for proposed timelines for PREA PMRs. The sponsor agreed to provide a response by close of business on September 30, 2010 and to follow-up with a formal submission of the response once the Agency has agreed to the proposed timelines.

The conversation ended amicably.

Addendum: The Agency electronically sent to the sponsor on September 28, 2010 the attached request for proposed timelines for PREA PMRs

**From:** Helm, Jeannine  
**Sent:** Tuesday, September 28, 2010 5:36 PM  
**To:** 'Jeff Troughton'  
**Cc:** Owens, Margo; Gould, Barbara  
**Subject:** NDA 022563 Sorilux- Request for proposed timelines of PREA postmarketing requirement trials

NDA 022563

Stiefel Laboratories, Inc.  
Attention: Jeffrey S. Troughton, MS, RAC  
Associate Director, Regulatory Affairs

Dear Mr. Troughton,

Please refer to your December 19, 2009, New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sorilux (calcipotriene) foam, 0.001%.

The Agency has identified the following Pediatric Research Equity Act (PREA) postmarketing requirement trials to be conducted post-approval:

1. A Pharmacokinetics/Pharmacodynamics trial of calcipotriene foam under maximal use conditions in 20 evaluable pediatric subjects with plaque psoriasis age 12 through 16 years. Evaluate the effect of the product on calcium metabolism in all subjects.

Final Protocol submission: Sponsor proposed  
Trial Completion: Sponsor proposed  
Final Report Submission: January, 2014

2. A Pharmacokinetics/Pharmacodynamics trial of calcipotriene foam under maximal use conditions in 25 evaluable pediatric subjects with plaque psoriasis age 2 through 11 years. Evaluate the effect of the product on calcium metabolism in all subjects.

Final Protocol submission: Sponsor proposed  
Trial Completion: Sponsor proposed  
Final Report Submission: January, 2014

3. A vehicle-controlled trial of the safety and efficacy of calcipotriene foam in 100 evaluable pediatric subjects with plaque psoriasis age 2 through 11 years. Evaluate the effect of the product on calcium metabolism in all subjects.

Final Protocol submission: Sponsor proposed  
Trial Completion: Sponsor proposed  
Final Report Submission: January, 2014

Send a letter containing proposed timelines for the above trials. We request receipt of your written response by close of business September 30, 2010.

You are encouraged to submit protocols to the IND for review prior to initiation the studies to assure that the proper design elements are incorporated. Each submission to the IND must be provided in triplicate (original plus two copies).

We remind you that all laboratory or animal studies intended to support the safety of this product should be conducted in compliance with the regulations for "Good Laboratory Practice for Nonclinical Laboratory Studies" (21 CFR Part 58).

If you have any questions, please contact me.

Thank you,  
Jeannine

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Jeannine M. Helm  
Regulatory Project Manager  
FDA/CDER/ODE III/DDDP  
Tel: 301.796.0637  
Fax: 301.796.9894/9895  
email: [Jeannine.Helm@fda.hhs.gov](mailto:Jeannine.Helm@fda.hhs.gov)

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Jeannine M. Helm  
Regulatory Project Manager  
FDA/CDER/ODE III/DDDP  
Tel: 301.796.0637  
Fax: 301.796.9894/9895  
email: [Jeannine.Helm@fda.hhs.gov](mailto:Jeannine.Helm@fda.hhs.gov)

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/s/

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TATIANA OUSSOVA  
10/05/2010

## MEMORANDUM OF TELECONFERENCE

**DATE:** August 31, 2010; 4:10 P.M.

**APPLICATION NUMBER:** NDA 022563 Sorilux™ (calcipotriene) foam, 0.001%

**INDICATION:** Topical treatment of plaque psoriasis in patients (b) (4)

**SPONSOR:** Stiefel Laboratories, Inc.

**FDA Attendees:**

Jill Lindstrom, M.D., Clinical Team Leader, DDDP  
Melinda McCord, M.D., Clinical Reviewer, DDDP  
Zachary Oleszczuk, PharmD., Team Leader, DMEPA  
Margo Owens, Project Management Team Leader, DDDP  
Jeannine Helm, Regulatory Health Project Manager, DDDP

**Sponsor Attendees:**

Jeffrey Troughton, MS, RAC, Associate Director, Regulatory Affairs  
Devon Allen, MS, RAC, Senior Director, Regulatory Affairs  
Salisa Hauptmann, MPH, Vice President, Global Regulatory Affairs and R&D Quality  
Alicia Tatro, Ph.D., Associate Director, Regulatory Affairs, Labeling & Ad/Promo  
Melanie Eatough, Associate Director, Regulatory Affairs Labeling

**SUBJECT:** Discussion of potential medication error and safety concerns regarding the styling and coloration of the sponsor proposed trade dress carton and container

**Background:**

This original NDA application, NDA 022563 Sorilux™ (calcipotriene) foam, 0.001%, was submitted December 19, 2010. The sponsor proposed carton and container labeling was provided in this submission and is the subject of this teleconference.

**The Agency presented the following discussion:**

- The Agency expressed concerns regarding the styling and coloration of the sponsor proposed trade dress carton and container and the potential medication error risk associated with the high similarity of the Sorilux proposed trade dress and an approved product's (Veltin) trade dress.
- The Agency noted that as topical products are stored in the same location in an isolated area of pharmacies and inpatient and outpatient settings, there could be a risk of selection error for drug products with similar packaging.

- The Agency further noted that there is also a medication error risk if patients are concurrently prescribed two drug products with correspondingly high trade dress styling and coloration similarity.

**The sponsor stated the following:**

- The sponsor stated that this was useful feedback and asked for suggestions from the Agency how to maintain branding but also support a change in labeling to clearly differentiate drug products.
  - The Agency replied that this change could be achieved with a change in color scheme.
- The sponsor stated that they would take these recommendations under advisement and would provide the Agency with revised carton and container labeling artwork by the September 10, 2010.

**Action Plan:**

The sponsor will officially submit a revised mock-up of the carton and container draft labeling by September 10, 2010.

The conversation ended amicably.

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

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NDA-22563

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ORIG-1

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STIEFEL  
LABORATORIES  
INC

-----  
CALCIPOTRIEN FOAM 0.005%

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JILL A LINDSTROM  
09/15/2010



NDA 022563

**INFORMATION REQUEST**

Stiefel Laboratories, Inc.  
Attention: Jeffrey S. Troughton, MS, RAC  
Associate Director, Regulatory Affairs  
20 T. W. Alexander Drive  
Research Triangle Park, NC 27709

Dear Mr. Troughton:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sorilux™ (calcipotriene) Foam, 0.005%.

We are reviewing the carton and container labeling of your submission and have the following comments and information requests. We request a written response by August 23, 2010.

1. The primary and secondary container/closure labels contain abbreviation "µg" to define units of measure. Revise the units of measure to use "mcg" for micrograms to reduce the risk of error. Provide colored mock-ups with indicated changes.
2. The dosage form, 'Foam', on the container label and carton labeling appears on a different line than the active ingredient 'calcipotriene'. The dosage form and active ingredient should appear on the same line. The presentation should appear as follows:

Sorilux  
(calcipotriene) Foam,  
0.005%

3. The principal display panel of the container labels and carton labeling do not state that this product is for topical use only. 21 CFR 201.100(b)(3) states that the route of administration should be present, if the product is not for oral use. To comply with 21 CFR 201.100(b)(3), add the statement 'For topical use only' on the principal display panel of the container labels and carton labeling.
4. Delete [redacted] (b) (4) on the container label and carton labeling. [redacted] (b) (4)
5. Delete [redacted] (b) (4) on the container label and carton labeling.
6. Delete the following statement on the container label and carton labeling:
  - [redacted] (b) (4)

7. The traddress for Sorilux<sup>™</sup> Foam is similar in presentation and color scheme to the traddress of another Steifel drug product, Veltin<sup>™</sup> Gel. We recommend differentiating the two products by the use of different colors or some other means.

If you have any questions, call Jeannine Helm, at (301) 796-0637.

Sincerely,

*{See appended electronic signature page}*

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22563	ORIG-1	STIEFEL LABORATORIES INC	CALCIPOTRIEN FOAM 0.005%

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/s/

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STANKA KUKICH  
08/19/2010  
Signing for Susan Walker, Division Director

**From:** Helm, Jeannine  
**Sent:** Thursday, June 10, 2010 5:39 PM  
**To:** 'jtroughton@stiefel.com'  
**Cc:** Owens, Margo; Gould, Barbara  
**Subject:** NDA 022563 Sorilux

Dear Jeff,

Regarding your phone inquiry today whether it would be acceptable to do the repeat microbial challenge test, as requested in the NDA 022563 Sorilux May 24, 2010 information request letter, at your lab facility and not at the manufacturing site, we have the following response:

- The requested repeat of the Antimicrobial Effectiveness Test (AET) (Information Request Letter of 5/24/2010, Item 1b) may be performed at your lab site. The study should use the same ingredients and container/closure system components as that used at the commercial manufacturing site. There should be no change in the formulation, fill volume, propellant mixture (b) (4) propane, (b) (4) n-butane, (b) (4) isobutene) or container pressurization.

If you have any questions, please let me know.

Thank you,  
Jeannine

---

Jeannine M. Helm  
Regulatory Project Manager  
FDA/CDER/ODE III/DDDP  
Tel: 301.796.0637  
Fax: 301.796.9894/9895  
email: [Jeannine.Helm@fda.hhs.gov](mailto:Jeannine.Helm@fda.hhs.gov)

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/s/

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JEANNINE M HELM  
09/20/2010

## MEMORANDUM OF TELECONFERENCE MINUTES

**TCON DATE:** June 1, 2010  
**APPLICATION:** NDA 022563  
**DRUG NAME:** Sorilux (calcipotriene) Foam, 0.005%  
**TYPE OF MEETING:** Information Request

**MEETING CHAIR:** Margo Owens

**MEETING RECORDER:** Jeannine Helm

### FDA ATTENDEES:

Margo Owens, Project Management Team Leader, DDDP  
Jeannine Helm, Regulatory Health Project Manager, DDDP

### EXTERNAL CONSTITUENT ATTENDEES:

Laurie Harris, Stiefel Laboratories, Inc.

### DISCUSSION POINTS:

1. The Agency requested that the sponsor submit a pediatric development plan for ages 2 to 18years old.
2. The sponsor asked if this plan was still needed [REDACTED] (b) (4)
3. The Agency confirmed that this submission should be part of the NDA application.
4. The Agency requested a Friday, June 4, 2010 due date for these studies. The sponsor stated that this may be a difficult date to meet and the Agency replied that the sponsor should consult their team and then respond back whether the due date could be met or with an alternate date.
5. The call ended amicably.

### ACTION ITEMS:

- The sponsor will submit a pediatric development plan by June 4, 2010. If this date is not feasible, the sponsor will contact the project manager with a new due date.

### Addendum:

The sponsor contacted the PM-TL for further clarification on the need for a pediatric plan. The PM-TL clarified that [REDACTED] (b) (4) we are requesting a pediatric plan.

The sponsor stated that they understand and they will work on submitting the plan as soon as possible. However, it is not likely that they will be able to meet the proposed date. The Agency requested an update on the response date as soon as possible.

The conversation ended amicably.

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

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NDA-22563

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ORIG-1

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STIEFEL  
LABORATORIES  
INC

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CALCIPOTRIEN FOAM 0.005%

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/s/  
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JEANNINE M HELM

06/24/2010



NDA 022563

**INFORMATION REQUEST**

Stiefel Laboratories, Inc.  
Attention: Jeffrey S. Troughton, MS, RAC  
Associate Director, Regulatory Affairs  
20 T. W. Alexander Drive  
Research Triangle Park, NC 27709

Dear Mr. Troughton:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sorilux<sup>™</sup> (calcipotriene) Foam, 0.005%.

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

1. Concerning the Antimicrobial Effectiveness Testing (AET), provide the following:
  - a. A detailed summary of the actual methods used for both the initial formulation development studies and for the studies on Lot XEF-C, Lot ZLS-C, Lot ZLT-C and Lot AEA-1.
  - b. A clarification of the microbial challenge, i.e., was the product challenge actually conducted in the final pressurized canister? If not, we recommend repeat testing in which canisters are filled with the bulk drug product and then inoculated with the microbial challenge, evacuated, sealed and pressurized with the proposed propellant mix.
2. Provide a detailed description of the test methods used for performing microbial limits testing for release of the final drug product.
3. *Burkholderia cepacia* is an opportunistic pathogen that is commonly found in water and soil. It is often present in commercial water systems as well as natural environments. Finished products that do not purport to be sterile are expected to meet the requirements of 21CFR211.113(a) *Control of microbiological contamination*. While USP <1111> provides recommended microbial limits for certain classes of non-sterile products, there should also be a risk assessment that addresses other objectionable microorganisms, including *B. cepacia*. Therefore, provide the following:

- Test methods and acceptance criteria to demonstrate the product is free of the objectionable microorganism *B. cepacia*. We recommend that potential sources are examined and sampled as process controls, and these may include raw materials and the manufacturing environment. A risk assessment for this species in the product and raw materials is recommended to develop sampling procedures and acceptance criteria. Your test method should be validated and a discussion of those methods should be provided. Test methods validation should address multiple strains of the species and cells that are acclimated to the environments (e.g., warm or cold water) that may be tested.
4. Describe the test protocol in detail and provide a final report for the 8-week in-use study. Include copies of the microbiological methods used, any qualification reports on the suitability of the assay methods, and data to include the actual plate counts observed at each time point.
  5.  (b) (4)

If you have any questions, call Jeannine M. Helm, Regulatory Project Manager, at (301) 796-0637.

Sincerely,

*{See appended electronic signature page}*

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

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

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NDA-22563

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STIEFEL  
LABORATORIES  
INC

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CALCIPOTRIEN FOAM 0.005%

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/s/  
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SUSAN J WALKER

05/24/2010



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SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

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Type/Number

Submitter Name

Product Name

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NDA-22563

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/s/  
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JEANNINE M HELM

05/11/2010



NDA 22563

**INFORMATION REQUEST**

Stiefel Laboratories, Inc.  
Attention: Jeffrey S. Troughton, MS, RAC  
Associate Director, Regulatory Affairs  
20 T. W. Alexander Drive  
Research Triangle Park, NC 27709

Dear Mr. Troughton:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sorilux<sup>TM</sup> (calcipotriene) Foam, 0.005%.

We are reviewing the clinical 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. Provide a graph that plots baseline BSA versus serum calcium increase and a graph that plots the amount of product used versus serum calcium increase.
2. Provide a table comparing the amount of drug exposure (<100 grams, 100-120 grams, >120 grams) versus the overall adverse events.
3. Provide information and an analysis of exposure to the moiety during pregnancy and associated pregnancy outcomes.

Please send your response no later than close of business May 17, 2010.

If you have any questions, call Jeannine M. Helm, Regulatory Project Manager, at (301) 796-0637.

Sincerely,

*{See appended electronic signature page}*

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

Application  
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Submission  
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Submitter Name

Product Name

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NDA-22563

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CALCIPOTRIEN FOAM 0.005%

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/s/  
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SUSAN J WALKER

05/11/2010



NDA 22563

## INFORMATION REQUEST

Stiefel Laboratories, Inc.  
Attention: Jeffrey S. Troughton, MS, RAC  
Associate Director, Regulatory Affairs  
20 T. W. Alexander Drive  
Research Triangle Park, NC 27709

Dear Mr. Troughton:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sorilux™ (calcipotriene) Foam, 0.005% for the treatment of psoriasis.

We are reviewing the clinical 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.

### Clinical/Biostatistics

1. To address the effect of your product on cardiac repolarization, please provide either data from a thorough QT/QTc study, or a rationale for why it is not needed.
2. Clarify the function(s) of light mineral oil, white petrolatum, and isopropyl myristate in the formulation. [REDACTED] (b) (4) is not a physiochemical function that an excipient serves in the product. Alternatively, a different description and function based on the physicochemical properties of these excipients in the product should be submitted with justification to the application.

We are also reviewing the draft labeling submitted in the Physician's Labeling Rule (PLR) format and have identified the following formatting issues:

### Regulatory Labeling Deficiencies

#### **In the Highlights section:**

1. For the Initial U.S. Approval, delete '2010' and replace with the four-digit year in which FDA initially approved the new molecular entity, new biological product, or new combination of active ingredients.

2. Remove 'and FDA-Approved Patient Labeling' from the following sentence: 'See 17 for PATIENT COUNSELING INFORMATION' and FDA-Approved Patient Labeling. FDA-Approved Patient Labeling is not part of Section 17 but can be included at the end of the Full Prescribing Information started on a separate page. Place the FDA-Approved Patient Labeling on a separate page after the Full Prescribing Information.
3. Delete the revision date, '12/2009' at the end of the Highlights. For a new NDA, the revision date should be left blank at the time of submission and be edited to the month/year of application approval.

**Between the Highlights and Table of Contents Sections:**

4. Add a horizontal line between the Highlights and Table of Contents sections. A horizontal line must be located between these sections.

**In the Contents (Table of Contents) section:**

5. Delete subsection, 17.1 Patient Package Insert. FDA-Approved Patient Labeling is not part of Section 17 but can be included at the end of the Full Prescribing Information started on a separate page.

**In the Full Prescribing Information:**

6. Add the statement, '*See FDA-Approved Patient Labeling.*' to section 17 PATIENT COUNSELING INFORMATION.
7. Delete '17.1 Patient Package Insert' and '-See below-'.

Address the identified labeling deficiencies/issues and re-submit labeling by May 7, 2010.

If you have any questions, call Jeannine M. Helm, Regulatory Project Manager, at (301) 796-0637.

Sincerely,

*{See appended electronic signature page}*

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

Application  
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Submission  
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Submitter Name

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NDA-22563

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STIEFEL  
LABORATORIES  
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CALCIPOTRIEN FOAM 0.005%

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SUSAN J WALKER

04/27/2010

# REQUEST FOR CONSULTATION

TO (Office/Division): Pediatric and Maternal Health Staff

FROM (Name, Office/Division, and Phone Number of Requestor):

Melinda McCord, MO, DDDP/ODE III, 301.796.2223  
Jill Lindstrom, Clinical TL, DDDP/ODE III,  
301.796.0944  
Jeannine M. Helm, RPM, DDDP/ODE III, 301.796.0637

DATE  
April 22, 2010

IND NO.

NDA NO.  
022563

TYPE OF DOCUMENT  
Original NDA

DATE OF DOCUMENT  
December 21, 2009

NAME OF DRUG  
Sorilux™ (calcipotriene)  
Foam, 0.005%

PRIORITY CONSIDERATION  
Standard

CLASSIFICATION OF DRUG

DESIRED COMPLETION DATE  
May 21, 2010

NAME OF FIRM: Stiefel Laboratories, Inc.

## REASON FOR REQUEST

### I. GENERAL

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> NEW PROTOCOL                    | <input type="checkbox"/> PRE-NDA MEETING         | <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER     |
| <input type="checkbox"/> PROGRESS REPORT                 | <input type="checkbox"/> END-OF-PHASE 2a MEETING | <input type="checkbox"/> FINAL PRINTED LABELING            |
| <input type="checkbox"/> NEW CORRESPONDENCE              | <input type="checkbox"/> END-OF-PHASE 2 MEETING  | <input type="checkbox"/> LABELING REVISION                 |
| <input type="checkbox"/> DRUG ADVERTISING                | <input type="checkbox"/> RESUBMISSION            | <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE       |
| <input type="checkbox"/> ADVERSE REACTION REPORT         | <input type="checkbox"/> SAFETY / EFFICACY       | <input type="checkbox"/> FORMULATIVE REVIEW                |
| <input type="checkbox"/> MANUFACTURING CHANGE / ADDITION | <input type="checkbox"/> PAPER NDA               | <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW): |
| <input type="checkbox"/> MEETING PLANNED BY              | <input type="checkbox"/> CONTROL SUPPLEMENT      |  |

### II. BIOMETRICS

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|---|---|
| <input type="checkbox"/> PRIORITY P NDA REVIEW  | <input type="checkbox"/> CHEMISTRY REVIEW       |
| <input type="checkbox"/> END-OF-PHASE 2 MEETING | <input type="checkbox"/> PHARMACOLOGY           |
| <input type="checkbox"/> CONTROLLED STUDIES     | <input type="checkbox"/> BIOPHARMACEUTICS       |
| <input type="checkbox"/> PROTOCOL REVIEW        | <input type="checkbox"/> OTHER (SPECIFY BELOW): |
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### III. BIOPHARMACEUTICS

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| <input type="checkbox"/> DISSOLUTION             | <input type="checkbox"/> DEFICIENCY LETTER RESPONSE  |
| <input type="checkbox"/> BIOAVAILABILITY STUDIES | <input type="checkbox"/> PROTOCOL - BIOPHARMACEUTICS |
| <input type="checkbox"/> PHASE 4 STUDIES         | <input type="checkbox"/> IN-VIVO WAIVER REQUEST      |

### IV. DRUG SAFETY

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

### V. SCIENTIFIC INVESTIGATIONS

- |                                   |                                      |
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| <input type="checkbox"/> CLINICAL | <input type="checkbox"/> NONCLINICAL |
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#### COMMENTS / SPECIAL INSTRUCTIONS:

This is an original NDA 022563 for Sorilux™ (calcipotriene) for the topical treatment of plaque psoriasis in patients (b) (4). The PDUFA date is October 21, 2010.

1. During Phase 2 and 3 studies only 7 subjects less than age 18 were exposed to calcipotriene foam and 3 exposed to vehicle foam. A single subject under the age of 18 was assessed for systemic exposure to calcipotriene foam.

- a. Does PMHS agree with the sponsor that the data collected in the Phase 2 and Phase 3 studies for NDA 22563 allow a determination of the safety and efficacy of calcipotriene foam in children ages 12 to 18?
- b. Should the Division request systemic exposure data in subjects age 12 to 18?

2. (b) (4) The Division is considering

a partial pediatric waiver below 2 years of age and a deferral for ages 2 to 12. Does PMHS agree with the DDDP plan to request that the sponsor study pediatric subjects age 2 years and above? Please recommend a lower age limit for study of psoriasis products in pediatric subjects.

Please refer to the attached material for background information.

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CAL 201 is the clinical bridge to findings of safety for Dovonex ointment. Since the listed drug was withdrawn by the time Phase 3 trials were conducted, a Dovonex ointment arm is not included in these trials.

(b) (4)

- Section 505(b)(a)(4)(B)(i): necessary studies are impossible or highly impracticable
- Section 505(b)(a)(4)(B)(iii):the drug or biological product-(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group, and (II) is not likely to be used by a substantial number of pediatric patients in that age group

However, data from a population –based study in the United Kingdom by Gelfand et al 1 provides an estimate of the prevalence of psoriasis in patients ages 9 and younger as 55.02 per 10,000. According to the United States Census data from 2000 2, there are 40 million individuals aged 9 years and younger. Thus, the estimated prevalence of psoriasis among patients in this age group in the United States is 220,000. This significantly exceeds the number defined by the Agency as “a substantial number of patients with a condition for which the drug is indicated, and for which pediatric studies would be required” even without the inclusion of patients aged 10 and 11. In addition, approved treatment options for children are limited to some corticosteroids that are labeled for use in the pediatric age group. These children are at risk for adverse events associated with chronic corticosteroid application. Therefore, a treatment option indicated for mild to moderate psoriasis in children greater than age 2 does represent a meaningful benefit over existing therapies and is consistent with recent department precedent.

(b) (4)

there were only 10 subjects less than 18 years old exposed to calcipotriene foam or its vehicle in Phase 2 or Phase 3 trials. However, it may be appropriate to apply for a partial waiver for studies in children less than 2 years of age based on the prevalence and safety issues related to their greater body surface area.

---

1 Gelfand JM et al. Prevalence and Treatment of Psoriasis in the United Kingdom: A Population-Based Study. Arch Dermatol 2005;141:1537-41.

2 U.S. Census Bureau. DP-1. Profile of General Demographic Characteristics:2000

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Product Name

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CALCIPOTRIEN FOAM 0.005%

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/s/  
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JEANNINE M HELM

04/22/2010

## Helm, Jeannine

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**From:** Helm, Jeannine  
**Sent:** Wednesday, April 21, 2010 5:04 PM  
**To:** Helm, Jeannine  
**Subject:** FW: NDA 22563 Sorilux MedDRA Version Question

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**From:** Helm, Jeannine  
**Sent:** Wednesday, April 21, 2010 12:26 PM  
**To:** 'Jeffrey Troughton'  
**Cc:** Owens, Margo; Gould, Barbara  
**Subject:** NDA 22563 Sorilux MedDRA Version Question

Hi Jeff,

I have two questions regarding the MedDRA version used in clinical trials for NDA 22563 Sorilux.

- Clarify which MedDRA version was used in the Phase 2 and Phase 3 trials?
- The integrated summary of safety includes studies, 201, 301 and 302. Were these adverse events recorded in the same MedDRA version?

Please respond by noon tomorrow, April 22, 2010 and follow-up with an official submission to your NDA.

Thank you,  
Jeannine

---

Jeannine M. Helm  
Regulatory Project Manager  
FDA/CDER/ODE III/DDDP  
Tel: 301.796.0637  
Fax: 301.796.9894/9895  
email: Jeannine.Helm@fda.hhs.gov

Application  
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Submission  
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Submitter Name

Product Name

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NDA-22563

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CALCIPOTRIEN FOAM 0.005%

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JEANNINE M HELM

04/21/2010



NDA 022563

**PROPRIETARY NAME REQUEST  
CONDITIONALLY ACCEPTABLE**

Stiefel, a GSK company  
20 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709

ATTENTION: Jeffrey S. Troughton, MS, RAC  
Associate Director, Regulatory Affairs

Dear Mr. Troughton:

Please refer to your New Drug Application (NDA) dated December 18, 2009, received December 21, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Calcipotriene Foam, 0.005%.

We also refer to your January 15, 2010, correspondence, received January 19, 2010, requesting review of your proposed proprietary name, Sorilux. We have completed our review of the proposed proprietary name, Sorilux, and have concluded that it is acceptable.

The proposed proprietary name, Sorilux, will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If **any** of the proposed product characteristics as stated in your January 15, 2010, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Janet Anderson, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-0675. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, Jeannine Helm at (301) 796-0637.

Sincerely,

*{See appended electronic signature page}*

Carol Holquist, RPh  
Director  
Division of Medication Error Prevention and Analysis  
Office of Surveillance and Epidemiology  
Center for Drug Evaluation and Research

Application  
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Submission  
Type/Number

Submitter Name

Product Name

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CALCIPOTRIEN FOAM 0.005%

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/s/  
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CAROL A HOLQUIST  
04/16/2010



NDA 22563

**INFORMATION REQUEST**

Stiefel Laboratories, Inc.  
Attention: Jeffrey S. Troughton, MS, RAC  
Associate Director, Regulatory Affairs  
20 T. W. Alexander Drive  
Research Triangle Park, NC 27709

Dear Mr. Troughton:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sorilux (calcipotriene) Foam, .005%.

We are reviewing the clinical data section of your submission and have the following information request. We request a prompt written response in order to continue our evaluation of your NDA by close of business April 22, 2010.

We have reviewed the referenced material and have the following requests for information.

- Provide analysis data sets for Study 201 which are similar in structure to those submitted for Studies 301 and 302.

If you have any questions, call Jeannine M. Helm at (301) 796-0637.

Sincerely,

*{See appended electronic signature page}*

Barbara J. Gould, MBAHCM  
Chief, Project Management Staff  
Division of Dermatology and Dental Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

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NDA-22563

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CALCIPOTRIEN FOAM 0.005%

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/s/  
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BARBARA J GOULD

04/09/2010

## REQUEST FOR CONSULTATION

TO (Office/Division): David Hussong/Jim McVey/Sylvia Gantt  
NEW DRUG MICROBIOLOGY STAFF  
OC/OO/CDER/OPS/NDMS - HFD-805

FROM (Name, Office/Division, and Phone Number of Requestor): Rajiv Agarwal, 301-796-1322 and Shulin Ding, 301-796-1349, through Jeannie David, Office of New Drug Quality Assessment, 301-796-4247

DATE March 10, 2010	IND NO.	NDA NO. 22-563	TYPE OF DOCUMENT Pending NDA	DATE OF DOCUMENT December 21, 2009
NAME OF DRUG Sorilux (calcipotriene) Foam, 0.005%		PRIORITY CONSIDERATION Standard review	CLASSIFICATION OF DRUG Topical for plaque psoriasis	DESIRED COMPLETION DATE May 7, 2010

NAME OF FIRM: Stiefel, a GSK Company

### REASON FOR REQUEST

#### I. GENERAL

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| <input type="checkbox"/> NEW PROTOCOL                    | <input type="checkbox"/> PRE-NDA MEETING         | <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER     |
| <input type="checkbox"/> PROGRESS REPORT                 | <input type="checkbox"/> END-OF-PHASE 2a MEETING | <input type="checkbox"/> FINAL PRINTED LABELING            |
| <input type="checkbox"/> NEW CORRESPONDENCE              | <input type="checkbox"/> END-OF-PHASE 2 MEETING  | <input type="checkbox"/> LABELING REVISION                 |
| <input type="checkbox"/> DRUG ADVERTISING                | <input type="checkbox"/> RESUBMISSION            | <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE       |
| <input type="checkbox"/> ADVERSE REACTION REPORT         | <input type="checkbox"/> SAFETY / EFFICACY       | <input type="checkbox"/> FORMULATIVE REVIEW                |
| <input type="checkbox"/> MANUFACTURING CHANGE / ADDITION | <input type="checkbox"/> PAPER NDA               | <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW): |
| <input type="checkbox"/> MEETING PLANNED BY              | <input type="checkbox"/> CONTROL SUPPLEMENT      |  |

#### II. BIOMETRICS

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| <input type="checkbox"/> PRIORITY P NDA REVIEW  | <input type="checkbox"/> CHEMISTRY REVIEW       |
| <input type="checkbox"/> END-OF-PHASE 2 MEETING | <input type="checkbox"/> PHARMACOLOGY           |
| <input type="checkbox"/> CONTROLLED STUDIES     | <input type="checkbox"/> BIOPHARMACEUTICS       |
| <input type="checkbox"/> PROTOCOL REVIEW        | <input type="checkbox"/> OTHER (SPECIFY BELOW): |
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#### III. BIOPHARMACEUTICS

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| <input type="checkbox"/> DISSOLUTION             | <input type="checkbox"/> DEFICIENCY LETTER RESPONSE  |
| <input type="checkbox"/> BIOAVAILABILITY STUDIES | <input type="checkbox"/> PROTOCOL - BIOPHARMACEUTICS |
| <input type="checkbox"/> PHASE 4 STUDIES         | <input type="checkbox"/> IN-VIVO WAIVER REQUEST      |

#### IV. DRUG SAFETY

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

#### V. SCIENTIFIC INVESTIGATIONS

- |                                   |                                      |
|-----------------------------------|--------------------------------------|
| <input type="checkbox"/> CLINICAL | <input type="checkbox"/> NONCLINICAL |
|-----------------------------------|--------------------------------------|

COMMENTS / SPECIAL INSTRUCTIONS: We request a Product Quality Micro review of this NDA. The NDA is electronically available at: \\CDSESUB1\EVSPROD\NDA022563\0022563.env.

This is an aerosol product. The formulation fails to meet USP<51>. The applicant addresses the issue of preservation in Section 3.2.P.2.2.1.4 and provides justification in Section 3.2.P.2.5. Please review and inform ONDQA whether the applicant's justification is adequate and the microbiological property of the proposed product is acceptable for NDA approval.

SIGNATURE OF REQUESTOR {see attached electronic signature}	METHOD OF DELIVERY (Check one) <input type="checkbox"/> DFS <input checked="" type="checkbox"/> EMAIL <input type="checkbox"/> MAIL <input type="checkbox"/> HAND
PRINTED NAME AND SIGNATURE OF RECEIVER	PRINTED NAME AND SIGNATURE OF DELIVERER

Application  
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Submitter Name

Product Name

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NDA-22563

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STIEFEL  
LABORATORIES  
INC

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CALCIPOTRIEN FOAM 0.005%

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/s/  
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JEANNIE C DAVID

03/10/2010



NDA 022563

**FILING COMMUNICATION**

Stiefel, a GSK Company  
Attention: Salisa Hauptmann, MPH, RAC  
Vice President, Global Regulatory Affairs  
20 T. W. Alexander Drive  
Research Triangle Park, NC 27709

Dear Ms. Hauptmann:

Please refer to your new drug application (NDA) dated December 18, 2009, received December 21, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for Sorilux™ (calcipotriene) Foam, 0.005%.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, in accordance with 21 CFR 314.101(a), this application is considered filed 60 days after the date we received your application. The review classification for this application is **Standard**. Therefore, the user fee goal date is October 21, 2010.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, midcycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process.

During our filing review of your application, we identified the following potential review issues:

**Clinical Pharmacology:**

1. The study population in the pharmacokinetics study does not sufficiently represent the age group of 12-18 years. The adequacy of data will be a review issue and may have an impact on the target patient population of your proposed product.

**Biostatistics:**

2. The site information included in Section 16.1.4 for Studies 301 and 302 is inadequate as it does not include the site number as provided in your SAS transport files.

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:

**CMC:**

1. A copy of Master Batch Record for review and a representative sample for dosage form evaluation.

**Biostatistics:**

2. A revised Section 16.1.4 for Studies 301 and 302 to include the site numbers along with investigator name and address. The site numbers provided in Section 16.1.4 should correspond to those provided in your electronic data sets (i.e. SAS transport files).

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.

**REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

(b) (4)



If you have any questions, call Jeannine M. Helm, Regulatory Project Manager, at (301) 796-0637.

Sincerely,

*{See appended electronic signature page}*

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

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CALCIPOTRIEN FOAM 0.005%

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/s/  
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SUSAN J WALKER  
02/26/2010

## REQUEST FOR DDMAC LABELING REVIEW CONSULTATION

**\*\*Please send immediately following the Filing/Planning meeting\*\***

TO: <b>CDER-DDMAC-RPM: Paul Loebach</b>	FROM: (Name/Title, Office/Division/Phone number of requestor) Melinda McCord, MO, DDDP/ODE III, 301.796.2223 Jill Lindstrom, Clinical TL, DDDP/ODE III, 301.796.0944 Jeannine M. Helm, RPM, DDDP/ODE III, 301.796.0637
--	---

REQUEST DATE February 5, 2010	IND NO.	NDA/BLA NO. 022563	TYPE OF DOCUMENTS Labeling (PLEASE CHECK OFF BELOW)
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NAME OF DRUG Sorilux™ (calcipotriene) Foam, 0.005%	PRIORITY CONSIDERATION Standard	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE (Generally 1 week before the wrap-up meeting) September 1, 2010
--	------------------------------------	------------------------	---

NAME OF FIRM: Stiefel, a GSK Company	PDUFA Date: October 21, 2010
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### TYPE OF LABEL TO REVIEW

<b>TYPE OF LABELING:</b> (Check all that apply) <input checked="" type="checkbox"/> PACKAGE INSERT (PI) <input checked="" type="checkbox"/> PATIENT PACKAGE INSERT (PPI) <input checked="" type="checkbox"/> CARTON/CONTAINER LABELING <input type="checkbox"/> MEDICATION GUIDE <input type="checkbox"/> INSTRUCTIONS FOR USE(IFU)	<b>TYPE OF APPLICATION/SUBMISSION</b> <input checked="" type="checkbox"/> ORIGINAL NDA/BLA <input type="checkbox"/> IND <input type="checkbox"/> EFFICACY SUPPLEMENT <input type="checkbox"/> SAFETY SUPPLEMENT <input type="checkbox"/> LABELING SUPPLEMENT <input type="checkbox"/> PLR CONVERSION	<b>REASON FOR LABELING CONSULT</b> <input checked="" type="checkbox"/> INITIAL PROPOSED LABELING <input type="checkbox"/> LABELING REVISION
---	--	---

**EDR link to submission:**  
<\\CDSESUB1\EVSPROD\NDA022563\022563.enx>

**Please Note: There is no need to send labeling at this time. DDMAC reviews substantially complete labeling, which has already been marked up by the CDER Review Team. The DDMAC reviewer will contact you at a later date to obtain the substantially complete labeling for review.**

COMMENTS/SPECIAL INSTRUCTIONS:

Mid-Cycle Meeting: TBD; around May 14, 2010

Labeling Meetings: TBD

Wrap-Up Meeting: TBD; around September 14, 2010

SIGNATURE OF REQUESTER

SIGNATURE OF RECEIVER	METHOD OF DELIVERY (Check one) <input checked="" type="checkbox"/> DARRTS <input type="checkbox"/> HAND
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Application  
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CALCIPOTRIEN FOAM 0.005%

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/s/  
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JEANNINE M HELM

02/22/2010



Application  
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JEANNINE M HELM

02/22/2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		<b>REQUEST FOR CONSULTATION</b>		
TO (Division/Office): <b>Mail: OSE/DMEPA</b>		FROM: Melinda McCord, MO, DDDP/ODE III, 301.796.2223 Jill Lindstrom, Clinical TL, DDDP/ODE III, 301.796.0944 Jeannine M. Helm, RPM, DDDP/ODE III, 301.796.0637		
DATE February 5, 2010	IND NO.	NDA NO. 022563	TYPE OF DOCUMENT Carton and container labels, PI, and PPI	DATE OF DOCUMENT December 21, 2010
NAME OF DRUG Sorilux™ (calcipotriene) Foam, 0.005%		PRIORITY CONSIDERATION Standard	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE September 1, 2010
NAME OF FIRM: Stiefel, a GSK Company				
<b>REASON FOR REQUEST</b>				
<b>I. GENERAL</b>				
<input type="checkbox"/> NEW PROTOCOL <input type="checkbox"/> PROGRESS REPORT <input type="checkbox"/> NEW CORRESPONDENCE <input type="checkbox"/> DRUG ADVERTISING <input type="checkbox"/> ADVERSE REACTION REPORT <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION <input type="checkbox"/> MEETING PLANNED BY		<input type="checkbox"/> PRE--NDA MEETING <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> SAFETY/EFFICACY <input type="checkbox"/> PAPER NDA <input type="checkbox"/> CONTROL SUPPLEMENT		<input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER <input type="checkbox"/> FINAL PRINTED LABELING <input type="checkbox"/> LABELING REVISION <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE <input type="checkbox"/> FORMULATIVE REVIEW <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW): Review of carton and container labels, PI, PPI
<b>II. BIOMETRICS</b>				
STATISTICAL EVALUATION BRANCH		STATISTICAL APPLICATION BRANCH		
<input type="checkbox"/> TYPE A OR B NDA REVIEW <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> CONTROLLED STUDIES <input type="checkbox"/> PROTOCOL REVIEW <input type="checkbox"/> OTHER (SPECIFY BELOW):		<input type="checkbox"/> CHEMISTRY REVIEW <input type="checkbox"/> PHARMACOLOGY <input type="checkbox"/> BIOPHARMACEUTICS <input type="checkbox"/> OTHER (SPECIFY BELOW):		
<b>III. BIOPHARMACEUTICS</b>				
<input type="checkbox"/> DISSOLUTION <input type="checkbox"/> BIOAVAILABILITY STUDIES <input type="checkbox"/> PHASE IV STUDIES		<input type="checkbox"/> DEFICIENCY LETTER RESPONSE <input type="checkbox"/> PROTOCOL-BIOPHARMACEUTICS <input type="checkbox"/> IN-VIVO WAIVER REQUEST		
<b>IV. DRUG EXPERIENCE</b>				
<input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL <input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below) <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP		<input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE <input type="checkbox"/> POISON RISK ANALYSIS		
<b>V. SCIENTIFIC INVESTIGATIONS</b>				
<input type="checkbox"/> CLINICAL		<input type="checkbox"/> PRECLINICAL		
COMMENTS/SPECIAL INSTRUCTIONS:  Please review the attached package insert, patient package insert, and carton and container labels.  PDUFA date: October 21, 2009				
SIGNATURE OF REQUESTER		METHOD OF DELIVERY (Check one) <input type="checkbox"/> MAIL <input type="checkbox"/> HAND		
SIGNATURE OF RECEIVER		SIGNATURE OF DELIVERER		

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CALCIPOTRIEN FOAM 0.005%

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/s/  
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JEANNINE M HELM

02/22/2010



NDA 022563

**NDA ACKNOWLEDGMENT**

Stiefel, a GSK Company  
Attention: Salisa Hauptmann, MPH, RAC  
Vice President, Global Regulatory Affairs  
20 T. W. Alexander Drive  
Research Triangle Park, NC 27709

Dear Ms. Hauptmann:

We have received your new drug application (NDA) submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: Sorilux<sup>™</sup> (calcipotriene) Foam, 0.005%

Date of Application: December 18, 2009

Date of Receipt: December 21, 2009

Our Reference Number: NDA 022563

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 February 19, 2010 in accordance with 21 CFR 314.101(a).

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must conform to the content and format requirements of revised 21 CFR 201.56-57.

The NDA number provided above should be cited 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

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm>

If you have any questions, call me, at (301) 796-0637.

Sincerely,

*{See appended electronic signature page}*

Jeannine M. Helm  
Regulatory Project Manager  
Division of Dermatology and Dental Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Application  
Type/Number

Submission  
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JEANNINE M HELM

01/08/2010