CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205555Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION[1]

NDA # 205555 BLA #	NDA Supplement # BLA Supplement #	If NDA, Efficacy Supplement Type: *(an action package is not required for SE8 or SE9 supplements)*
Proprietary Name: STERITALC® Established/Proper Name: Talc Dosage Form: Powder		Applicant: Novatech S.A. Agent for Applicant (if applicable): Boston Medical Products Inc.
RPM: Elleni Alebachew		Division:

NDA Application Type: ☐ 505(b)(1) ☒ 505(b)(2)
Efficacy Supplement: ☐ 505(b)(1) ☐ 505(b)(2)

BLA Application Type: ☐ 351(k) ☐ 351(a)
Efficacy Supplement: ☐ 351(k) ☐ 351(a)

For ALL 505(b)(2) applications, two months prior to EVERY action:

- **Review the information in the 505(b)(2) Assessment and submit the draft[2] to CDER OND IO for clearance.**
- **Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity)**

☒ No changes
☐ New patent/exclusivity *(notify CDER OND IO)*
Date of check:

Note: 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.

❖ Actions	
• Proposed action April 28, 2017 • User Fee Goal Date is May 14, 2017	☒ AP ☐ TA ☐ CR
• Previous actions *(specify type and date for each action taken)*	☐ None
❖ If accelerated approval or approval based on efficacy studies in animals, were promotional materials received? Note: Promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf). If not submitted, explain	☐ Received
❖ Application Characteristics[3]	

[1] The **Application Information** Section is (only) a checklist. The **Contents of Action Package** Section (beginning on page 2) lists the documents to be included in the Action Package.
[2] For resubmissions, 505(b)(2) applications must be cleared before the action, but it is not necessary to resubmit the draft 505(b)(2) Assessment to CDER OND IO unless the Assessment has been substantively revised (e.g., new listed drug, patent certification revised).
[3] 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.

Review priority: ☒ Standard ☐ Priority
Chemical classification (new NDAs only):
(confirm chemical classification at time of approval)

☐ Fast Track
☐ Rolling Review
☒ Orphan drug designation
☐ Breakthrough Therapy designation
☐ Rx-to-OTC full switch
☐ Rx-to-OTC partial switch
☐ Direct-to-OTC

(NOTE: Set the submission property in DARRTS and notify the CDER Breakthrough Therapy Program Manager; Refer to the "RPM BT Checklist for Considerations after Designation Granted" for other required actions: CST SharePoint)

NDAs: Subpart H
☐ Accelerated approval (21 CFR 314.510)
☐ Restricted distribution (21 CFR 314.520)
Subpart I
☐ Approval based on animal studies

BLAs: Subpart E
☐ Accelerated approval (21 CFR 601.41)
☐ Restricted distribution (21 CFR 601.42)
Subpart H
☐ Approval based on animal studies

☐ Submitted in response to a PMR
☐ Submitted in response to a PMC
☐ Submitted in response to a Pediatric Written Request

REMS: ☐ MedGuide
☐ Communication Plan
☐ ETASU
☐ MedGuide w/o REMS
☐ REMS not required

Comments:

❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 *(approvals only)*	☐ Yes ☐ No
❖ Public communications *(approvals only)*	
• Office of Executive Programs (OEP) liaison has been notified of action	☐ Yes ☒ No
• Indicate what types (if any) of information were issued	☒ None ☐ FDA Press Release ☐ FDA Talk Paper ☐ CDER Q&As ☐ Other
❖ Exclusivity	
• Is approval of this application blocked by any type of exclusivity (orphan, 5-year NCE, 3-year, pediatric exclusivity)? • If so, specify the type	☒ No ☐ Yes
❖ Patent Information (NDAs only)	
• Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought.	☒ Verified ☐ Not applicable because drug is an old antibiotic.

CONTENTS OF ACTION PACKAGE

Officer/Employee List

❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list *(approvals only)*	☒ Included
Documentation of consent/non-consent by officers/employees	☒ Included

Action Letters	
❖ Copies of all action letters *(including approval letter with final labeling)*	Action(s) and date(s) May 1, 2017
Labeling	
❖ Package Insert *(write submission/communication date at upper right of first page of PI)*	
• Most recent draft labeling *(if it is division-proposed labeling, it should be in track-changes format)*	☒ Included 4/24/2017
• Original applicant-proposed labeling	☒ Included 4/15/2016
❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling *(write submission/communication date at upper right of first page of each piece)*	☐ Medication Guide ☐ Patient Package Insert ☐ Instructions for Use ☐ Device Labeling ☒ None
• Most-recent draft labeling *(if it is division-proposed labeling, it should be in track-changes format)*	☐ Included
• Original applicant-proposed labeling	☐ Included
❖ Labels (**full color** carton and immediate-container labels) *(write submission/communication date on upper right of first page of each submission)*	
• Most-recent draft labeling	☒ Included 1/6/2017
❖ Proprietary Name • Acceptability/non-acceptability letter(s) *(indicate date(s))* • Review(s) *(indicate date(s)*	11/7/2016- Acceptability letter 11/01/2016 - Review
❖ Labeling reviews *(indicate dates of reviews)*	RPM: ☐ None 8/4/2016 DMEPA: ☐ None 12/13/2016; 1/13/2017 DMPP/PLT (DRISK): ☒ None OPDP: ☐ None 2/8/2017 SEALD: ☒ None CSS: ☒ None Product Quality ☒ None Other: ☒ None
Administrative / Regulatory Documents	
❖ RPM Filing Review[4]/Memo of Filing Meeting *(indicate date of each review)* ❖ All NDA 505(b)(2) Actions: Date each action cleared by 505(b)(2) Clearance Committee	7/22/2016 ☐ Not a (b)(2) 3/23/2017
❖ NDAs/NDA supplements only: Exclusivity Summary *(signed by Division Director)*	☒ Completed (Do not include)
❖ Application Integrity Policy (AIP) Status and Related Documents http://www fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm	
• Applicant is on the AIP	☐ Yes ☒ No

[4] Filing reviews for scientific disciplines are NOT required to be included in the action package.

• This application is on the AIP o If yes, Center Director's Exception for Review memo *(indicate date)* o If yes, OC clearance for approval *(indicate date of clearance communication)*	☐ Yes ☒ No ☐ Not an AP action
❖ Pediatrics *(approvals only)* • Date reviewed by PeRC If PeRC review not necessary, explain:	N/A Orphan Designated
❖ Breakthrough Therapy Designation	☒ N/A
• Breakthrough Therapy Designation Letter(s) (granted, denied, an/or rescinded)	
• CDER Medical Policy Council Breakthrough Therapy Designation Determination Review Template(s) *(include only the completed template(s) and not the meeting minutes)*	
• CDER Medical Policy Council Brief – Evaluating a Breakthrough Therapy Designation for Rescission Template(s) *(include only the completed template(s) and not the meeting minutes)* *(completed CDER MPC templates can be found in DARRTS as clinical reviews or on the MPC SharePoint Site)*	
❖ Outgoing communications: letters, emails, and faxes considered important to include in the action package by the reviewing office/division (e.g., clinical SPA letters, RTF letter, Formal Dispute Resolution Request decisional letters, etc.) *(do not include OPDP letters regarding pre-launch promotional materials as these are non-disclosable; do not include Master File letters; do not include previous action letters, as these are located elsewhere in package)*	3.17.17 1.31.17 1.27.17 1.17.17 1.17.17 1.6.17 1.4.17 12.16.16 12.14.16 11.23.16 11.15.16 11.7.16 10.31.16 10.26.16 10.19.16 9.28.16 9.21.16 9.16.16 9.14.16 9.13.16 9.9.16 8.18.16 7.27.16 (2) 6.23.16 4.27.16 4.20.16
❖ Internal documents: memoranda, telecons, emails, and other documents considered important to include in the action package by the reviewing office/division (e.g., Regulatory Briefing minutes, Medical Policy Council meeting minutes)	12/29/2016 10/7/2016
❖ Minutes of Meetings	
• If not the first review cycle, any end-of-review meeting *(indicate date of mtg)*	☒ N/A or no mtg
• Pre-NDA/BLA meeting *(indicate date of mtg)*	☐ No mtg

• EOP2 meeting *(indicate date of mtg)*	☐ No mtg
• Mid-cycle Communication *(indicate date of mtg)*	☐ N/A
• Late-cycle Meeting *(indicate date of mtg)*	☐ N/A
• Other milestone meetings (e.g., EOP2a, CMC focused milestone meetings) *(indicate dates of mtgs)*	
❖ Advisory Committee Meeting(s)	☒ No AC meeting
• Date(s) of Meeting(s)	
Decisional and Summary Memos	
❖ Office Director Decisional Memo *(indicate date for each review)*	☒ None
Division Director Summary Review *(indicate date for each review)*	☐ None 5.1.17
Cross-Discipline Team Leader Review *(indicate date for each review)*	☐ None 4/26/2017
PMR/PMC Development Templates *(indicate total number)*	☒ None
Clinical	
❖ Clinical Reviews	
• Clinical Team Leader Review(s) *(indicate date for each review)*	☒ No separate review Refer to Primary review dated 3/6/2017
• Clinical review(s) *(indicate date for each review)*	Filing clinical review-6/10/2016 Primary clinical review-3/6/2017 --------- DPARP consult memo-9/6/2016 OSE consult memo-6/10/2016 CDRH consult memo-5/10/2016
• Social scientist review(s) (if OTC drug) *(indicate date for each review)*	☒ None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here ☒ and include a review/memo explaining why not *(indicate date of review/memo)*	Refer to Clinical review dated 3/6/2017 Page 17 .
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers *(indicate date of each review)*[5]	☒ None
❖ Controlled Substance Staff review(s) and Scheduling Recommendation *(indicate date of each review)*	☒ N/A
❖ Risk Management • REMS Documents and REMS Supporting Document *(indicate date(s) of submission(s))* • REMS Memo(s) and letter(s) *(indicate date(s))* • Risk management review(s) and recommendations (including those by OSE and CSS) *(indicate date of each review and indicate location/date if incorporated into another review)*	N/A ☐ None
❖ OSI Clinical Inspection Review Summary(ies) *(include copies of OSI letters to investigators)*	☒ None requested

[5] For Part 3 combination products, all reviews from the reviewing Center(s) should be entered into the official archive (for further instructions, see "Section 508 Compliant Documents: Process for Regulatory Project Managers" located in the CST electronic repository).

Clinical Microbiology ☒ None	
❖ Clinical Microbiology Team Leader Review(s) *(indicate date for each review)*	☐ No separate review
Clinical Microbiology Review(s) *(indicate date for each review)*	☐ None
Biostatistics ☒ None	
❖ Statistical Division Director Review(s) *(indicate date for each review)*	☐ No separate review
Statistical Team Leader Review(s) *(indicate date for each review)*	☐ No separate review
Statistical Review(s) *(indicate date for each review)*	☐ None
Clinical Pharmacology ☐ None	
❖ Clinical Pharmacology Division Director Review(s) *(indicate date for each review)*	☒ No separate review
Clinical Pharmacology Team Leader Review(s) *(indicate date for each review)*	☒ No separate review Refer to Primary Review Dated 1/13/2017
Clinical Pharmacology review(s) *(indicate date for each review)*	☐ None Primary Review: 1/13/2017 Filing Review: 6/3/2016
❖ OSI Clinical Pharmacology Inspection Review Summary *(include copies of OSI letters)*	☒ None requested
Nonclinical ☐ None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) *(indicate date for each review)*	☒ No separate review
• Supervisory Review(s) *(indicate date for each review)*	☒ No separate review Refer to Primary review dated 4/24/2017
• Pharm/tox review(s), including referenced IND reviews *(indicate date for each review)*	☐ None Primary Review: 4/24/2017; Filing Review: 6/20/2016
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer *(indicate date for each review)*	☒ None
❖ Statistical review(s) of carcinogenicity studies *(indicate date for each review)*	☒ No carc
❖ ECAC/CAC report/memo of meeting	☒ None Included in P/T review, page
❖ OSI Nonclinical Inspection Review Summary *(include copies of OSI letters)*	☒ None requested
Product Quality ☐ None	
❖ Product Quality Discipline Reviews[6]	
• Tertiary review (*indicate date for each review*)	☒ None
• Secondary review (e.g., Branch Chief) *(indicate date for each review)*	☒ None Refer IQA review dated 4/25/2017
• Integrated Quality Assessment (contains the Executive Summary and the primary reviews from each product quality review discipline) *(indicate date for each review)*	☐ None 4/25/2017
❖ Reviews by other disciplines/divisions/Centers requested by product quality review team *(indicate date of each review)*	☐ None Refer IQA review dated 4/25/2017

[6] Do not include Master File (MF) reviews or communications to MF holders. However, these documents should be made available upon signatory request.

❖ Environmental Assessment (check one) (original and supplemental applications)	
☒ Categorical Exclusion *(indicate review date)(all original applications and all efficacy supplements that could increase the patient population)*	Refer IQA review dated 4/25/2017
☐ Review & FONSI *(indicate date of review)*	
☐ Review & Environmental Impact Statement *(indicate date of each review)*	
❖ Facilities Review/Inspection	
☒ Facilities inspections (indicate date of recommendation; within one week of taking an approval action, confirm that there is an acceptable recommendation before issuing approval letter) *(only original applications and efficacy supplements that require a manufacturing facility inspection(e.g., new strength, manufacturing process, or manufacturing site change)*	☒ Acceptable Refer IQA review dated 4/25/2017 ☐ Withhold recommendation ☐ Not applicable

Day of Approval Activities	
❖ For all 505(b)(2) applications: • Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity)	☒ No changes ☐ New patent/exclusivity *(Notify CDER OND IO)*
• Finalize 505(b)(2) assessment	☒ Done
❖ For Breakthrough Therapy (BT) Designated drugs: • Notify the CDER BT Program Manager	☐ Done *(Send email to CDER OND IO)*
❖ For products that need to be added to the flush list (generally opioids): Flush List • Notify the Division of Online Communications, Office of Communications	☐ Done
❖ Send a courtesy copy of approval letter and all attachments to applicant by fax or secure email	☐ Done
❖ If an FDA communication will issue, notify Press Office of approval action after confirming that applicant received courtesy copy of approval letter	☐ Done
❖ Ensure that proprietary name, if any, and established name are listed in the *Application Product Names* section of DARRTS, and that the proprietary name is identified as the "preferred" name	☒ Done
❖ Ensure Pediatric Record is accurate	☐ Done
❖ Send approval email within one business day to CDER-APPROVALS	☒ Done

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/s/

ELLENI K ALEBACHEW
05/02/2017

Cottrell, Christy L.

From: Cottrell, Christy L.
Sent: Tuesday, April 11, 2017 11:04 AM
To: 'j.neff@bessgroup.com'
Cc: Alebachew, Elleni; Leahy, Kristine
Subject: NDA 205555 for Steritalc: FDA proposed labeling revisions
Attachments: 4-11-17 FDA revised PI Steritalc NDA 205555.docx

Importance: High

Dr. Neff,

Please refer to your pending NDA 205555 for Steritalc. Attached are the Division's proposed edits to the labeling. Please accept all changes that you agree with and use "track changes" to delineate any counterproposals you may have. We respectfully request your response to this labeling **by Tuesday, April 18, 2017**.

Feel free to contact me with any questions, as I am covering for Elleni Alebachew this week.

Best regards,
Christy Cottrell

Christy Cottrell
Chief, Project Management Staff

Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-4256
Fax: 301-796-9845
christy.cottrell@fda.hhs.gov

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

Reference ID: 4082714

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/s/

CHRISTY L COTTRELL
04/11/2017

From:	Alebachew, Elleni
To:	"Neff, Jennifer"
Cc:	"Stuart Montgomery"
Subject:	NDA 205555 - Information Request
Date:	Friday, March 17, 2017 4:16:00 PM
Attachments:	image001.png
Importance:	High

Dear Dr. Neff,

Please refer to your April 14, 2016, resubmission to your new drug application (NDA), submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for STERITALC® (Talc). We also refer to your amendments dated December 9, 2016, January 9, 30, 2017 and March 8, 2017.

We note that your submissions do not comply with 21 CFR 314.60(f), which was added by the final rule on Abbreviated New Drug Applications and 505(b)(2) Applications; Final Rule, 81 FR 69580 (October 6, 2016). The final rule became effective on **December 5, 2016**.

Section 314.60(f) requires that an amendment to an unapproved 505(b)(2) application contain an appropriate patent certification or statement described in 21 CFR 314.50(i), or a "recertification" for a previously submitted paragraph IV certification, if approval is sought for changes described in any of the following types of amendments:

- To add a new indication or other condition of use;
- To add a new strength;
- To make other than minor changes in product formulation; or
- To change the physical form or crystalline structure of the active ingredient.

If an amendment to the 505(b)(2) application does not contain a patent certification (or recertification) or statement, the applicant must verify that the proposed change described in the amendment is not one of the types of amendments described above.

We recommend that the cover letter for your response to this information request and for future amendments to your unapproved 505(b)(2) application either:

1) states that the amendment contains a patent certification (or recertification) or statement required by 21 CFR 314.60(f)(1); or
2) verifies that the proposed change described in the amendment is not one of the types of amendments described in 21 CFR 314.60(f)(1), as appropriate.

Please respond by March 22, 2017. Your response to this information request must clearly reference your amendments dated December 9, 2016, January 9, 30, 2017 and March 8, 2017.

If you have any questions, please contact me and kindly respond to confirm receipt of this communication.

Regards,

Elleni Alebachew, MS, RAC

Senior Regulatory Health Project Manager

Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-5225
Fax: 301-796-9845
elleni.alebachew@fda.hhs.gov

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/s/

ELLENI K ALEBACHEW
03/17/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

REVIEW EXTENSION – MAJOR AMENDMENT

Novatech S.A.
c/o Boston Medical Products Inc.
Attention: Stuart K. Montgomery
President
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

Please refer to your New Drug Application (NDA) dated April 14, 2016, received April 14, 2016, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for STERITALC® (Talc) Powder, 2g, 3g, and 4g.

On January 9, 2017, we received your January 6, 2017, major amendment to this application. Therefore, we are extending the goal date by three months to provide time for a full review of the submission. The extended user fee goal date is **May 14, 2017**.

In addition, we are establishing a new timeline for communicating labeling changes and/or postmarketing requirements/commitments in accordance with PDUFA reauthorization performance goals and procedures – fiscal years 2013 through 2017. We note that labeling discussions have already commenced and are ongoing. If major deficiencies are not identified during our review, we plan to communicate any postmarketing requirement/commitment requests by **April 14, 2017**.

If you have any questions, call Elleni Alebachew, Regulatory Project Manager, at (301) 796-5225.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

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

/s/

AMNA IBRAHIM
01/31/2017

MEMORANDUM OF TELECONFERENCE

Teleconference Date: January 25, 2017, 12:00 PM EST

Application Number: NDA 205555
Product Name: Novatech S.A
Applicant Name: Talc powder- STERITALC®

FDA Participants :
Amna Ibrahim, MD, Deputy Director, DOP1
Yarery Smith, Ph.D., Senior Review Microbiologist, OPQ
Jesse Wells, Ph.D., Microbiology Team Lead, OPQ
Elleni Alebachew, MS, RAC, Regulatory Project Manager, DOP1

Applicant Participants

Martin Gördes, CTO & Director Quality Management, bess pro gmbh
Jennifer Neff, DVM, PhD., Regulatory & Medical Affairs, bess AG

RE : Validation of the depyrogenation process

Per Novatech request, on 01/25/2017 a tcon took place between the referenced staff from the Agency and Novatech regarding the validation of the depyrogenation process for the 10 mL and 50 mL glass vials proposed for commercial production.

(b) (4) Novatech committed to March 7, 2017 as the deadline to submit to the Agency the results from the depyrogenation study.

Post-meeting comment: The Agency asks Novatech to provide an update on the progress of the referenced depyrogenation study via **Tcon on 02/14/2017, 11:30pm-12:00pm, EST**.

Furthermore, Novatech (and/or any Consultant representing Novatech) is greatly encouraged to reach out to the Agency's review team for advice, if needed.

If you have any questions, call me at (301) 796 5225.

Sincerely,

{See appended electronic signature page}

Elleni Alebachew, MS, RAC
Senior Regulatory Health Project Manager
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

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/s/

ELLENI K ALEBACHEW
01/27/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

INFORMATION REQUEST

Novatech S. A.
c/o Boston Medical Products, Inc.
Attention: Stuart Montgomery, President
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

Please refer to your April 15, 2016, New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Steritalc® (Talc) Powder, 2g, 3g, and 4g.

We are reviewing the Chemistry, Manufacturing, and Controls sections 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.

Drug Product:

1. The following statement needs to be added in both carton and vial labels: "Single-dose vial. Discard unused portion."
2. The NDC # in the carton label should appear prominently in the top third of the principal display panel per 21 CFR 207.35(b)(3)(i).

If you have any questions, please contact me, at (240) 402-5834 or email me: Kristine.Leahy@fda.hhs.gov. Please respond to comments by COB **January 23, 2017.**

Sincerely,

Kristine F. Leahy -S

Digitally signed by Kristine F. Leahy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001815977, cn=Kristine F. Leahy -S
Date: 2017.01.17 15:52:10 -05'00'

Kristine Leahy, RPh.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Kristine Leahy

Digitally signed by Kristine Leahy
Date: 1/17/2017 03:55:29PM
GUID: 55f72bd9003d99948f388d681cbec17d

From:	Alebachew, Elleni
To:	"Neff, Jennifer"
Cc:	smontgomery@bosmed.com
Subject:	NDA 205555 FDA Revised PI
Date:	Tuesday, January 17, 2017 10:13:00 PM
Attachments:	image013.png NDA 205555 propossed PI FDA Revised-7.17.17.docx

Dear Dr. Neff,

The purpose of this email is to provide you with the updated version of the label (attached) for your review. Please provide your comments/revisions no later than **Wednesday, January 25, 2017**. Please be sure that all of your changes are captured in track changes, and that you accept all of the changes we made that you agree to.

Please note there are still outstanding review issues and we are hoping to discuss them during the Thursday teleconference.

Let me know if you have any questions.

Regards,

Elleni Alebachew, MS, RAC
Senior Regulatory Health Project Manager

Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-5225
Fax: 301-796-9845
elleni.alebachew@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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

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/s/

ELLENI K ALEBACHEW
01/17/2017

From: Leahy, Kristine
To: "Neff, Jennifer"
Cc: "Stuart Montgomery"
Subject: FDA Information Request NDA 205555-please respond TODAY or by COB 1-9-17
Date: Friday, January 06, 2017 11:41:00 AM
Attachments: image001.png
Importance: High

Dear Jennifer,

Our Review Team has the following *time-sensitive* information request:

> Add appearance test by visual inspection along with acceptance criterion in your proposed drug product and drug substance specifications. Please update the specification tables accordingly in both drug substance and drug product sections.

Your response is requested by *COB today*, but no later than COB on 01/09/2017.

Thank you,

Kristine

Kristine F. Leahy, RPh.

Regulatory Business and Process Manager

HHS | FDA | CDER

Office Of Pharmaceutical Quality (OPQ)

Office Of Program and Regulatory Operations (OPRO)

10903 New Hampshire Ave| WO75| Room 4507|

Silver Spring, MD 20993

Ph: 240-402-5834

Kristine.leahy@fda.hhs.gov

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***FDA requires the use of secure email for all communications that may include proprietary information.*
To establish, please contact secureemail@fda.hhs.gov

Kristine Leahy

Digitally signed by Kristine Leahy
Date: 1/06/2017 02:10:20PM
GUID: 55f72bd9003d99948f388d681cbec17d

From:	Alebachew, Elleni
To:	"Neff, Jennifer"
Cc:	smontgomery@bosmed.com
Subject:	Steritalc (NDA 205555) - Information Request
Date:	Wednesday, January 04, 2017 3:31:00 PM
Attachments:	image002.png
Importance:	High

Dear Dr. Neff,

Reference is made to your container label and carton labeling received on December 28, 2016. Please respond to the information request below by **no later than January 10, 2016.**

-

Please confirm receipt.

A. General recommendations
   1. Since your product is available as a dry powder, revise the strength presentation to express the strength in terms of the total amount of drug per vial as follows: "# g/vial" or "# g per vial".[a]

B. Carton labeling
   1. As currently presented, the blue wave-like graphic has more prominence than the proprietary name. Reduce the size of the graphic to ensure that the graphic does not compete in prominence with important product information.[a]

[a] Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors. Food and Drug Administration. 2013. Available from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM349009.pdf

Regards,

Elleni Alebachew, MS, RAC
Senior Regulatory Health Project Manager

Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-5225
Fax: 301-796-9845
elleni.alebachew@fda.hhs.gov

APPEARS THIS WAY ON ORIGINAL

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/s/

ELLENI K ALEBACHEW
01/04/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

INFORMATION REQUEST

Novatech S. A.
c/o Boston Medical Products, Inc.
Attention: Stuart Montgomery, President
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

Please refer to your April 15, 2016, New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Steritalc® (Talc) Powder, 2g, 3g, and 4g.

We are reviewing the Chemistry, Manufacturing, and Controls sections 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.

- Based on the risk assessment you submitted on 12/9/2016, the drug product specification for lead of (b) (4) ppm, or (b) (4) µg/g, is not justified. It is our understanding that USP will be revising individual product specific monographs to comply with the PDEs for elemental impurities in ICH Q3D, so it is not adequate to rely on the USP monograph for talc which sets the limit for lead at (b) (4) µg/g at this time. A limit of (b) (4) µg/g of lead in the drug product appears to be supported based on your calculation of an adjusted PDE for lead in talc with a maximum potential dose of 10 g in adult patients. According to the data you presented on lead testing in your drug product, the highest level detected was (b) (4) µg/g. Revise your drug product specification to include a limit of NMT (b) (4) ppm for lead.

If you have any questions, please contact me, at (240) 402-5834 or email me: Kristine.Leahy@fda.hhs.gov.

Please respond to comments by COB **January 19, 2017.**

Sincerely,

Kristine F. Leahy -S

Digitally signed by Kristine F. Leahy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001815977, cn=Kristine F. Leahy -S
Date: 2016.12.16 16:41:52 -05'00'

Kristine Leahy, RPh.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

INFORMATION REQUEST

Novatech S. A.
c/o Boston Medical Products, Inc.
Attention: Stuart Montgomery, President
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

Please refer to your April 15, 2016, New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Steritalc® (Talc) Powder, 2g, 3g, and 4g.

We are reviewing the Chemistry, Manufacturing, and Controls sections 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.

Microbiology:

1. With regard to the container closure integrity test (CCIT), per the Agency's *Guidance for Industry for the Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products*, information from scientific validation studies (and data) in support of the microbial integrity of the drug packaging components are to be submitted for review prior to the approval of the application. The following information should be provided: a brief narrative clearly describing the performance of a CCIT that uses a sensitive detection method, the study/report # and date, the results for all the test and control units (i.e., positive, negative, purposely breached, etc), indication of how the positive control was prepared, the identity of the content in the test units, the acceptance criteria for the validation, and the sensitivity of the test. Please note that for dye ingress methods, the method should be able to detect ingress of < (b)(4) µL of dye, though detection of < (b)(4) µL is preferred. An objective method of detection, such as spectrophotometry is also preferred. Furthermore, please note that the CCIT studies should be performed with the exact same stoppers that will be used for the commercial production of the drug product and with vials with the same internal neck

dimensions as the vials used for the commercial production of the drug product.

2. With regard to the depyrogenation of the subject glass bottles, it is acknowledged that bess pro gmbh is in contact with a subcontractor for the cleaning and packaging of the vials with, or that the vials will be depyrogenated at bess pro gmbh using a [redacted] It is further acknowledged that that Novatech SA will provide an update about the status of this decision on December 22, 2016. However, please note that as stated in the Agency's *Guidance for Industry for the Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products*, information from scientific validation studies (and data) in support of the depyrogenation processes for the drug packaging components are to be submitted for review prior to the approval of the application. Consequently, please provide the methods and data (including controls) from three successful validation runs demonstrating the efficacy of the depyrogenation of the glass bottles to be used for commercial production. At a minimum, the following information should be provided, run ID #(s) and dates of performance; requalification cycle parameters and acceptance criteria; a description of the load(s); a description/depiction of the locations of endotoxin indicators (EIs), complete EI information (genus/species, lot, manufacturer, and expiry), amount of EI added to the challenge and positive/negative control units, the type endotoxin detection test method and [redacted] sensitivity, and the recovery results from the challenge and control units.

3. With regard to the bacterial endotoxins specification, on page 6 of the document "NOV_USA_STERITALC_Response Document_final_20161206.pdf", it is stated that the specification is [redacted] EU/mg; respectively [redacted] EU/g"; however, the updated CoA for the drug product indicates that the bacterial endotoxins specification for release of commercial batches is "Less than [redacted] EU/g". Please explain this discrepancy, and provide an updated CoA as applicable.

4. With regard to the bacterial endotoxins testing (BET) for release of commercial batches of the drug product, on page 1 of the document [redacted]. In addition, the results provided ("Laboratory evaluation") pertain only to the test for interfering factors, but the actual [redacted] results for the drug product were not provided. Please provide validation results from the BET method validation. The following information should be included:

a) A brief narrative of the BET procedure that includes the description of the sample (b) (4) validation process that should be performed given that the drug product is not soluble.
b) The MVD calculation with the sensitivity value of the actual (b) (4) used for the pertaining test.
c) Inhibition/enhancement (I/E) studies that were performed to determine that the drug product does not interfere with the detection of endotoxins. These studies should indicate i) the product concentration used, ii) the product dilutions tested, iii) the sensitivity of the (b) (4) and iv) the results of I/E testing as well as the (b) (4) test results for the drug product. If a (b) (4) was used, indicate the absolute value of the correlation coefficient and the percent recovery for the positive controls.
d) Indicate the dilution and the product concentration (in mg/mL) that will be used for routine testing for release of all the drug product configurations.
e) Provide revised Certificates of Analysis (CoA) of finished drug product lots that include the proposed BET specification in EU/mg or EU/g and the actual BET value obtained, as applicable.

5. For the "implementation of the test", it is stated that (b) (4) were used. Please clarify if the two referenced samples were pooled and justify your response. Please note that pooling samples results in an additional dilution equal to the number of pooled samples (in this case an additional (b) (4) fold dilution), should only one sample exceed the bacterial endotoxins specification; thus, the effect of pooling samples should be taken into account on the MVD for Bacterial Endotoxins testing method validation and routine testing of commercial batches.

6. With regard to the bacterial endotoxins specification for the stability program, on page 12 of the document (b) (4) it is stated that the criteria is "Less than (b) (4) EU/mg"; however, a different bacterial endotoxins specification has been proposed for release of commercial batches. Please explain this discrepancy and provide updated stability documentation, as well as BET validation information/data as applicable.

If you have any questions, or require a teleconference for a microbiology discussion regarding these Information Requests, please contact me, at (240) 402-5834 or email me at Kristine.Leahy@fda.hhs.gov.

Please respond to Microbiology comments by COB **January 5, 2017.**

Sincerely,

Kristine F. Leahy -S

Digitally signed by Kristine F. Leahy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001815977, cn=Kristine F. Leahy -S
Date: 2016.12.14 12:01:24 -05'00'

Kristine Leahy, RPh.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Kristine Leahy

Digitally signed by Kristine Leahy
Date: 12/14/2016 12:06 08PM
GUID: 55f72bd9003d99948f388d681cbec17d

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

INFORMATION REQUEST

Novatech S. A.
c/o Boston Medical Products, Inc.
Attention: Stuart Montgomery, President
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

Please refer to your April 15, 2016, New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Steritalc® (Talc) Powder, 2g, 3g, and 4g.

We are reviewing the Chemistry, Manufacturing, and Controls sections 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.

Drug Product:

Your justification for the proposed specification for lead of (b) (4) ppm, or (b) (4) µg/g, is not adequate. The risk assessment provided does not actually address the level of potential risk from lead in patients receiving Steritalc at the maximum administered dose. Provide a risk assessment of the relevant concerns for lead at the proposed specification at the maximum proposed dose of Steritalc in the intended patient population, which should include the following:

1. Describe the amounts of lead that have been detected in the drug substance and drug product of Steritalc as they relate to the proposed specification.

2. Specify the maximum amount of lead that the intended patients will be exposed to at your proposed specification for lead at (b) (4) µg/g in Steritalc.

3. Provide your risk assessment and detailed justification for exceeding the permitted daily exposure (PDE) of (b) (4) µg/g for lead specified in ICH Q3D guideline. This should include a risk assessment for typical real-world use of Steritalc at the recommended daily dose as well as the worst case scenario addressing the potential for bilateral administration of

multiple doses at the same time, repeated administrations in the same patient, and use in pediatric patients.

4. Provide an adequate justification for not conducting additional controls for lead content in Steritalc.

If you have any questions, please contact me, at (240) 402-5834 or email me at Kristine.Leahy@fda.hhs.gov. Please respond to Drug Product comments by **COB December 2, 2016.**

Sincerely,

Kristine F. Leahy -S

Digitally signed by Kristine F. Leahy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001815977, cn=Kristine F. Leahy -S
Date: 2016.11.23 11:05:47 -05'00'

Kristine Leahy, RPh.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Kristine Leahy

Digitally signed by Kristine Leahy
Date: 11/23/2016 11:10 32AM
GUID: 55f72bd9003d99948f388d681cbec17d

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

INFORMATION REQUEST

Novatech S. A.
c/o Boston Medical Products, Inc.
Attention: Stuart Montgomery, President
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

Please refer to your April 15, 2016, New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Steritalc® (Talc) Powder, 2g, 3g, and 4g.

We are reviewing the Chemistry, Manufacturing, and Controls sections 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.

Drug Product:

1. On page 12 of the updated report entitled "risk assessment and control of elemental impurities", you have corrected the errors we pointed out to you during PAI. We have noticed additional errors: Pb limit and content in tables 12, 13 and 14. Please scan through your document and correct any other errors in the document. **Please respond to Drug Product comments by COB November 18, 2016.**

Microbiology:

1. It is acknowledged that a CCIT was performed (b) (4)

(b) (4)

(b) (4)

[redacted]

(b) (4)

(b) (4)

(b) (4) **Please respond to Microbiology comments by COB December 6, 2016.**

If you have any questions, please contact me, at (240) 402-5834 or email me at Kristine.Leahy@fda.hhs.gov.

Sincerely,

Kristine F. Leahy -S

Digitally signed by Kristine F. Leahy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001815977, cn=Kristine F. Leahy -S
Date: 2016.11.15 16:43:32 -05'00'

Kristine Leahy, RPh.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Kristine Leahy

Digitally signed by Kristine Leahy
Date: 11/15/2016 04:53:45PM
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE

Novatech S.A.
c/o Boston Medical Products Inc.
70 Chestnut Street
Shrewsbury, MA 01545

ATTENTION: Stuart K. Montgomery
President

Dear Mr. Montgomery:

Please refer to your New Drug Application (NDA) dated April 14, 2016, received April 14, 2016, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Talc Powder, 2g, 3g, and 4g.

We also refer to your correspondence, dated and received August 19, 2016, requesting review of your proposed proprietary name, Steritalc.

We have completed our review of the proposed proprietary name, Steritalc and have concluded that it is conditionally acceptable.

If any of the proposed product characteristics as stated in your August 19, 2016, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review. Additionally, if your application receives a complete response, a new request for name review for your proposed name should be submitted when you respond to the application deficiencies.

If you require information on submitting requests for proprietary name review or PDUFA performance goals associated with proprietary name reviews, we refer you to the following:

- Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf)
- PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, (http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Frances Fahnbulleh, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301)796-0942. For any other information regarding this application, contact Elleni Alebachew, Regulatory Project Manager in the Office of New Drugs at (301)796-5225.

Sincerely,

{See appended electronic signature page}

Todd Bridges, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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/s/

LUBNA A MERCHANT on behalf of TODD D BRIDGES
11/07/2016

From: Alebachew, Elleni
To: "Neff, Jennifer"
Subject: Steritalc (NDA 205555) - Information Request Clinical
Date: Friday, October 28, 2016 8:49:00 AM
Importance: High

Hi Jennifer,

Please respond the clinical information request below by November 3, 2016.

In your email response dated Sept 9, 2016, to a Clinical Information Request, you provided tables listing all the countries in which Steritalc is marketed. Please clarify if "Korea" refers to North Korea, South Korea, or both. Steritalc was approved in "Korea" Nov. 2015 as a pharmaceutical, (b) (4) Please provide an update of safety reporting for 2016 from "Korea" when available

Please confirm receipt.

Regards,

Elleni Alebachew, MS, RAC
Senior Regulatory Health Project Manager
Division of Oncology Products 1
Office of Hematology and Oncology Products
FDA/ CDER/OND
E-mail: Elleni.Alebachew@fda.hhs.gov
Phone: (301) 796-5225
Fax: (301) 796-9845

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/s/

ELLENI K ALEBACHEW
10/31/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

INFORMATION REQUEST

Novatech S. A.
c/o Boston Medical Products, Inc.
Attention: Stuart Montgomery, President
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

Please refer to your April 15, 2016, New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Steritalc® (Talc) Powder, 2g, 3g, and 4g.

We are reviewing the Chemistry, Manufacturing, and Controls sections 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.

Drug Substance:

1. Include relative percentage composition of Talc (b) (4) (b) (4) specification. Explain how these percentages are determined, and provide the adequate justification for the numerical values specified.

2. (b) (4)

3. Include acceptance criteria for Particle Size Distribution in stability specification of Talc API, instead of Report Results.

4. Consolidate Stability Study Report of Talc API batches in a Tabular format.

Drug Product:

5. In your amendment 0008, dated 10/12/2016,
You indicate that the drug product specification for (b) (4) is identical, therefore you have provided same specification table for (b) (4). However,

in the specification table, you have proposed the acceptance criterion for the testing of uniformity of dosage units as "Has to comply with USP <905> weight variation regarding label claim 4.0 g" which only applies to (b) (4) Please correct it accordingly.

6. You indicated that you submitted batch analysis data for all three strengths ((STERITALC® (b) (4) (LOT 24276, 24294, 25072), STERITALC® (b) (4) (LOT 24217, 24277, 24311), STERITALC® (b) (4) (LOT 24126, 24248, 24310)) manufactured from one of the drug substance development batches (b) (4) However, we could not locate the data. Please provide the detail location of the data so we can locate and review the data.

7. On page 5 of the report entitled "risk assessment and control of elemental impurities", you indicate that talc includes a natural lead content. However, you did not provide any data or justification why there are no other Class (b) elemental impurities, i.e., (b) (4) present in talc. Please provide data or justification accordingly.

(b) (4)

If you have any questions, please contact me, at (240) 402-5834 or email me at Kristine.Leahy@fda.hhs.gov. **Please respond by COB November 2, 2016.**

Sincerely,

Kristine F. Leahy -S

Digitally signed by Kristine F. Leahy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001815977, cn=Kristine F. Leahy -S
Date: 2016.10.26 16:50:58 -04'00'

Kristine Leahy, RPh.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

From: Fahnbulleh, Frances
Sent: Wednesday, October 19, 2016 9:41 AM
To: Neff, Jennifer
Cc: Alebachew, Elleni
Subject: Steritalc (NDA 205555) - Information Request to clarify [redacted] (b) (4) for Steritalc

Dear Jennifer:

We refer to your Request for Proprietary Name Review submitted on August 19, 2016, in which the proposed proprietary name of the drug is "STERITALC". We also refer to your proposed Prescribing Information (PI) submitted on August 19, 2016, where the proposed drug product is referred to as [redacted] (b) (4) throughout the proposed PI.

It appears [redacted] (b) (4) corresponds to the strengths, 2 gram, 4 gram, and 3 gram, respectively.

Please clarify the proposed proprietary name you seek for review.
Additionally, please provide an explanation for intended meaning/use of [redacted] (b) (4)

Please provide your response by Tuesday, October 25, 2016.

Respectfully,
Frances

Frances Fahnbulleh, RPh, PharmD
Safety Regulatory Project Manager
Office of Surveillance and Epidemiology
CDER/FDA/WO22 , Rm#4404
Ph: 301-796-0942/Fax: 301-796-9832
Email: Frances.Fahnbulleh@fda.hhs.gov

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/s/

FRANCES G FAHNBULLEH
10/19/2016

Internal Meeting Minutes

Subject: OPQ Review Team Meeting, NDA 205555 Steritalc® (Talc), Powder, 2g, 3g, and 4g

Sponsor: Novatech S.A.

Time: Friday, 9/23/2016

Location: WO Bldg 51, Room 1215

Participants:

Lawrence Yu, Larisa Wu, Tom Oliver, Peter Qiu, Haripada Sarker, Yarery Smith, Marion Michaelis, Gerlie Gieser, Nina Ni, Giuseppe Randazzo, Brian Hasselbalch, Anamitro Banerjee, Xiao Chen, Bogdan Kurtyka, Tanya Clayton, Kristine Leahy.

Background information:

NDA 205555 has previously been submitted to the Agency. It received a Refuse to File on May 3, 2013 and was resubmitted April 14, 2016 and filed on June 13, 2016. The PDUFA due date for this application is February 15, 2017. (b) (4)

(b) (4)

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/s/

KRISTINE F LEAHY
10/07/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

INFORMATION REQUEST

Novatech S. A.
c/o Boston Medical Products, Inc.
Attention: Stuart Montgomery, President
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

Please refer to your April 15, 2016, New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Steritalc® (Talc) Powder, 2g, 3g, and 4g.

We are reviewing the Chemistry, Manufacturing, and Controls sections 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.

Drug Product:

1. For administration of you product, provide the following information:
    a. The proposed PI indicates that (b) (4) and (b) (4) may also be delivered as poudrage. Provide information on how to deliver (b) (4) and (b) (4) as poudrage.
    b. Provide detailed description of dosing preparation procedure on how to prepare different talc dose, i.e., 1 g, 2 g, 3 g, 4 g, and 5 g administered as either slurry or poudrage. Provide in-use data to demonstrate accurate dose is administered. Provide justification or data to demonstrate sterility of dosing suspension or poudrage is maintained during the dosing preparation procedure.
    c. Justify why (b) (4) when (b) (4)

2. Regarding the drug product specifications, provide the following:
    a. Provide drug product specifications for each strength of drug product. You have only provided one specification in the submission without specifying the drug product strength.
    b. In the proposed specification Table 3.2.P.5.1-1, the proposed acceptance criterion for the testing of uniformity of dosage units: "Has to comply with USP <905>

weight variation regarding label claim 4.0 (b) (4)". Please correct the unit.

c. Provide risk assessment and indicate any necessary controls on elemental impurities as per ICH Q3 (D).

3. You have indicated that all testing methods are compendial for the drug product. Verify these methods as per 21 CFR 211.194 (a) (2) and USP <1226> Verification of Compendial Procedures.

4. You have only provided batch release and stability data for (b) (4). Provide batch analysis and stability data for at least one batch of (b) (4) and (b) (4)

5. [redacted] (b) (4)

If you have any questions, please contact me, at (240) 402-5834 or email me at Kristine.Leahy@fda.hhs.gov. **Please respond by COB October 6, 2016.**

Sincerely,

Kristine F. Leahy -S

Digitally signed by Kristine F. Leahy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001815977, cn=Kristine F. Leahy -S
Date: 2016.09.28 14:41:07 -04'00'

Kristine Leahy, RPh.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

PROPRIETARY NAME ACKNOWLEDGEMENT

Novatech S.A.
C/O Boston Medical Products Inc.
70 Chestnut Street
Shewsbury, MA 01545

ATTENTION: Stuart Montgomery
President

Dear Mr. Montgomery:

Please refer to your New Drug Application (NDA) dated and received April 14, 2016, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Talc Powder, 2g, 3g, and 4g.

We acknowledge receipt of your correspondence dated and received August 19, 2016, requesting a review of your proposed proprietary name, Steritalc.

The user fee goal date is November 17, 2016.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact me at (301) 796-0942. For any other information regarding this application, contact Elleni Alebachew, Regulatory Project Manager, in the Office of New Drugs at (301) 796-5225.

Sincerely,

{See appended electronic signature page}

Frances Fahnbulleh, PharmD, RPh.
Safety Regulatory Project Manager
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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/s/

FRANCES G FAHNBULLEH
09/21/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

INFORMATION REQUEST

Novatech S. A.
c/o Boston Medical Products, Inc.
Attention: Stuart K. Montgomery, President
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

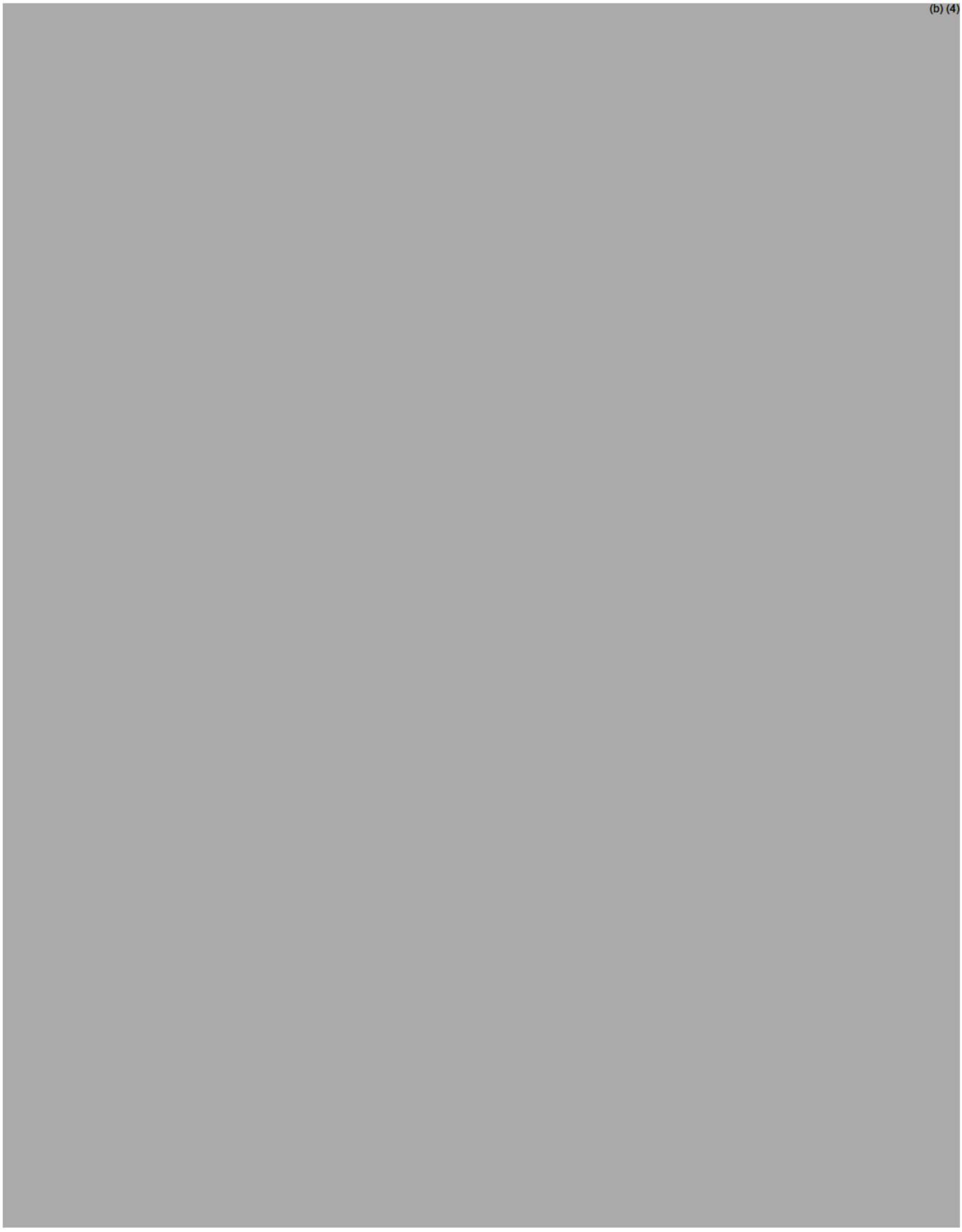
Please refer to your April 15, 2016, New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Steritalc® (talc powder), 2g, 3g, and 4g.

We are reviewing the Chemistry, Manufacturing, and Controls sections 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.

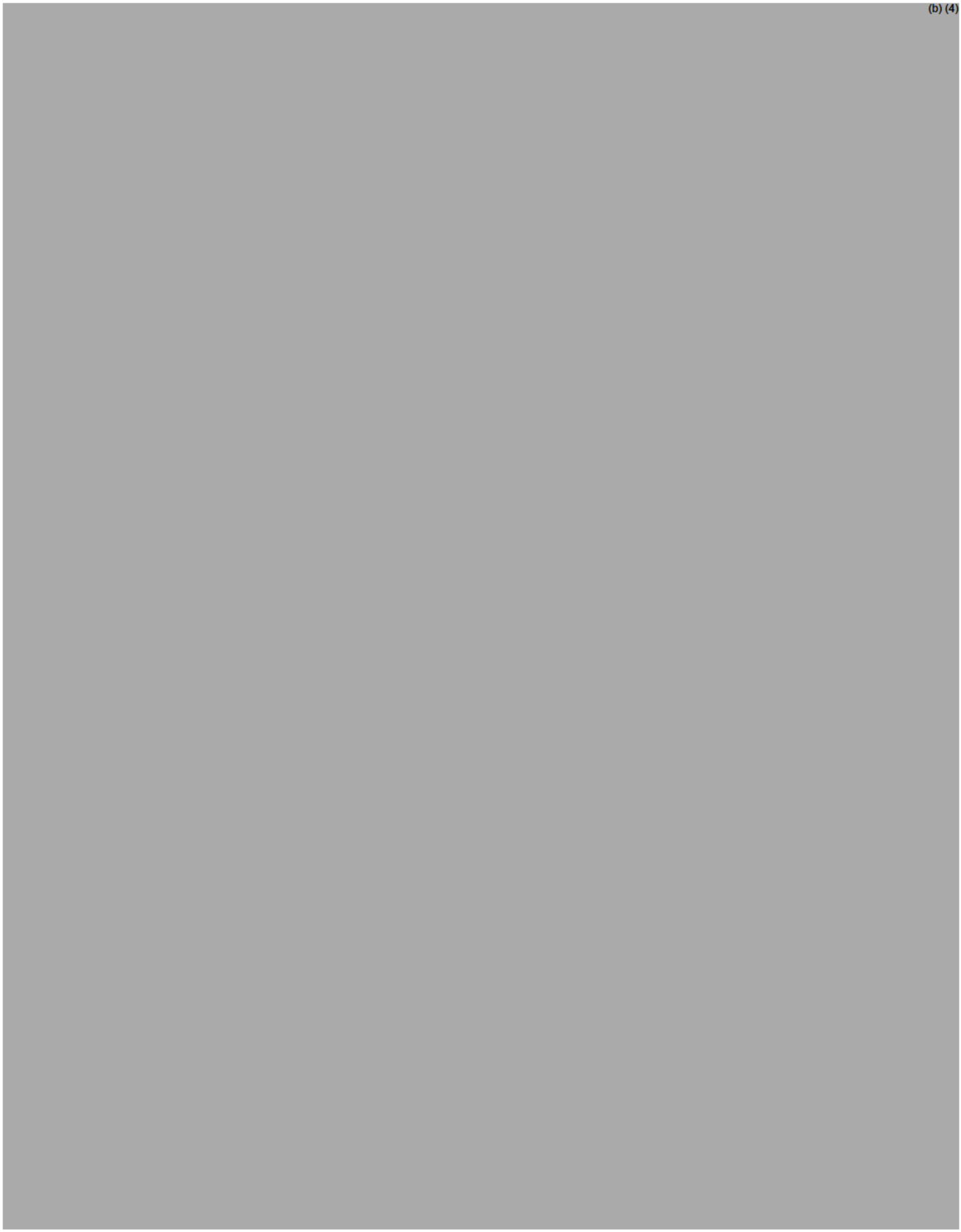
Microbiology:

1. The information regarding the container closure integrity test (CCIT) could not be located. Provide a brief narrative describing the CCIT method, the study/report # and date, the results for all the test and control units, indication of how the positive control was prepared, the identity of the media in the test units, the acceptance criteria for the validation, and the sensitivity of the test. (b) (4) (b) (4) (b) (4) (b) (4) (b) (4)

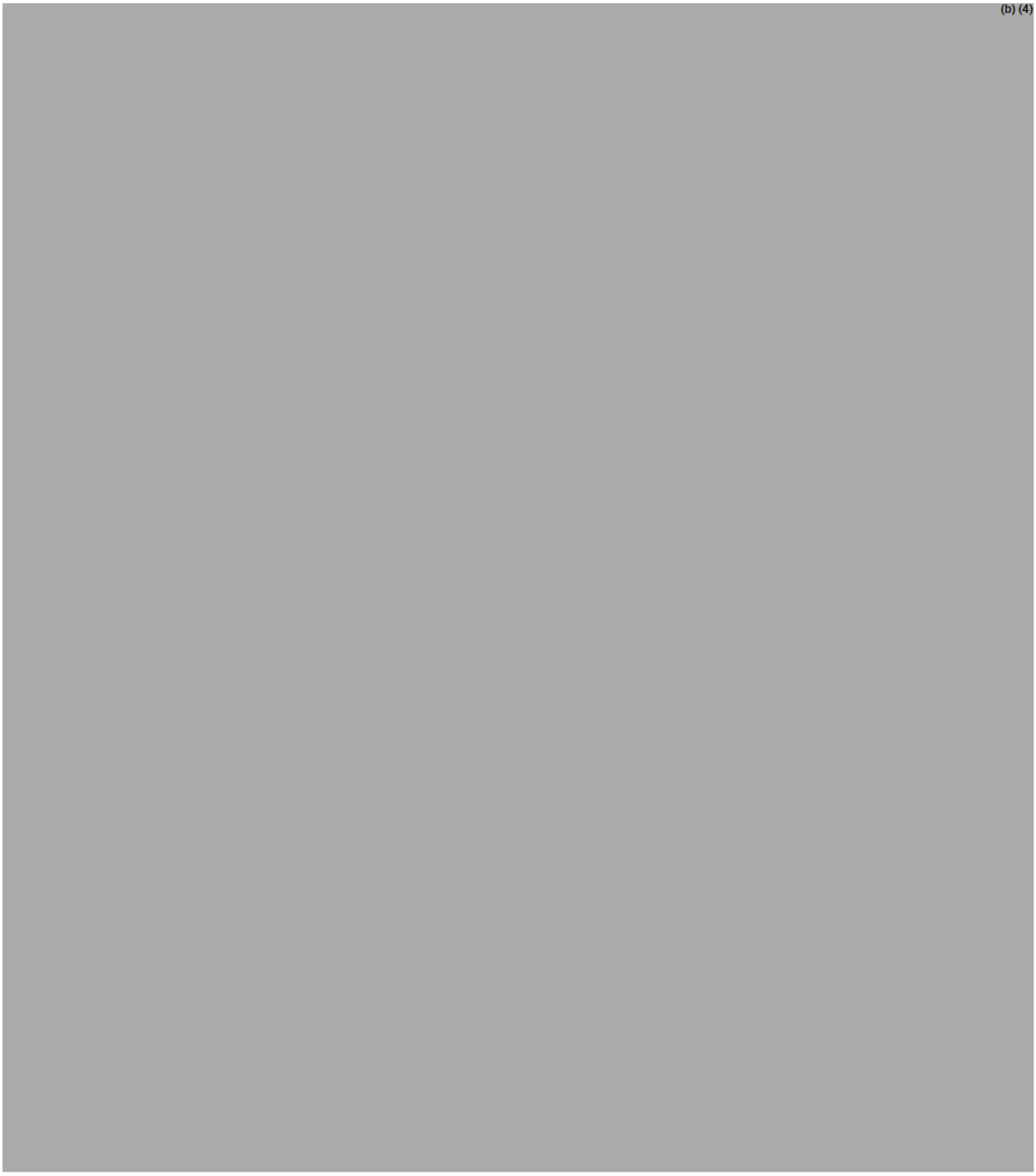
(b) (4)



(b) (4)



(b) (4)



If you have any questions, please contact me, at (240) 402-5834 or email me at Kristine.Leahy@fda.hhs.gov. **Please respond by COB October 16, 2016.**

Sincerely,

Kristine F. Leahy -S

Digitally signed by Kristine F. Leahy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001815977, cn=Kristine F. Leahy -S
Date: 2016.09.16 14:14:34 -04'00'

Kristine Leahy, RPh.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Kristine Leahy

Digitally signed by Kristine Leahy
Date: 9/16/2016 02:44:22PM
GUID: 55f72bd9003d99948f388d681cbec17d

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

INFORMATION REQUEST

Novatech S. A.
c/o Boston Medical Products, Inc.
Attention: Stuart Montgomery, President
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

Please refer to your April 15, 2016, New Drug Application (NDA) submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Steritalc® (Talc) Powder, 2g, 3g, and 4g.

We also refer to your response to FDA's information request received on September 8, 2016.

Our requests are listed below:

Facilities:

(b) (4)

Drug Substance:

4. In summary Table 3.2.S.4.4- 2 for CoA of DS batches, the acceptance criteria for Particle Size Distribution are indicated as (b) (4)

(b) (4) . (b) (4)

(b) (4)

7. Provide DP release data for the DP registration batches (Figure 2.3.P.8.1-1) utilized for stability studies by Novatech.

If you have any questions, please call me, at (240) 402-5834 or email me, at Kristine.Leahy@fda.hhs.gov. **Please respond to Drug Substance and Facilities comments by COB September 20, 2016.**

Sincerely,

{See appended electronic signature page}

Kristine Leahy, RPh.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Kristine Leahy

Digitally signed by Kristine Leahy
Date: 9/14/2016 11:28:01AM
GUID: 55f72bd9003d99948f388d681cbec17d

From: Alebachew, Elleni
To: "Neff, Jennifer"
Cc: "Stuart Montgomery"
Subject: NDA 205555-Clinical Information Request
Date: Tuesday, September 13, 2016 4:00:00 PM
Importance: High

Hello,

Below please find information request from the Clinical Review team. Please provide your response by **COB Thursday, September 15, 2016.**

Please clarify if your talc product marketed in Europe and elsewhere [redacted] (b) (4)

Please confirm receipt.

Regards,

Elleni Alebachew, MS, RAC
Senior Regulatory Health Project Manager
Division of Oncology Products 1
Office of Hematology and Oncology Products
FDA/ CDER/OND
E-mail: Elleni.Alebachew@fda.hhs.gov
Phone: (301) 796-5225
Fax: (301) 796-9845

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/s/

ELLENI K ALEBACHEW
09/13/2016

From: Alebachew, Elleni
To: Jennifer Neff (j.neff@bessgroup.com)
Cc: "Stuart Montgomery"
Subject: NDA 205555-Clinical Information Request
Date: Friday, September 09, 2016 5:33:00 PM
Importance: High

Hello,

Below please find information request from the Clinical Review team. Please provide your response by **COB Friday, September 16, 2016.**

In your NDA submission for Steritalc, you state there has only been a single safety report since 2008. Please provide a list of all the countries in which Steritalc is marketed and the year that authorization commenced. Please summarize in a table all post-marketing safety reports related to Steritalc by year and country.

Please confirm receipt.

Regards,

Elleni Alebachew, MS, RAC
Senior Regulatory Health Project Manager
Division of Oncology Products 1
Office of Hematology and Oncology Products
FDA/ CDER/OND
E-mail: Elleni.Alebachew@fda.hhs.gov
Phone: (301) 796-5225
Fax: (301) 796-9845

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/s/

ELLENI K ALEBACHEW
09/09/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

INFORMATION REQUEST

Novatech S. A.
Attention: Stuart Montgomery
President Boston Medical Products, Inc.
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

Please refer to your April 15, 2016, New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Steritalc® (Talc) Powder, 2g, 3g, and 4g.

We also refer to our August 16, 2016, teleconference during which we discussed concerns regarding the readiness for inspection of your facilities. During this teleconference, we committed to providing you with deficiencies in writing.

Our requests are listed below:

1. In the FDA Form 356h dated June 6, 2016, you indicated that (b) (4) Talc, (b) (4) are ready for inspection. In preparation for pre-approval inspections as part of your NDA 205555 application, FDA received information from these two sites that they are not ready/willing to be inspected by FDA.

(b) (4)

(b) (4)

We remind you that, although secure email between CDER and sponsors is useful for informal communications and courtesy copies of official communications, it cannot be a substitute for an official submission. When responding to this letter, please submit it through the FDA Electronic Gateway.

If you have any questions, please call me, at (240) 402-5834 or email me, at Kristine.Leahy@fda.hhs.gov.

Sincerely,

Kristine F. Leahy -S

Digitally signed by Kristine F. Leahy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001815977, cn=Kristine F. Leahy -S
Date: 2016.08.17 22:28:06 -04'00'

Kristine Leahy, RPh.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Kristine Leahy

Digitally signed by Kristine Leahy
Date: 8/18/2016 03:06:52PM
GUID: 55f72bd9003d99948f388d681cbec17d

From: Leahy, Kristine
To: "Stuart Montgomery"
Cc: "Jennifer Neff"; Alebachew, Elleni
Subject: FDA Drug Product Request-Samples- NDA 205555 STERITALC
Date: Tuesday, July 26, 2016 2:10:00 PM

Attachments: image001.png

Dear Stuart,

To facilitate our review of the NDA, the FDA will conduct a comprehensive analysis of your proposed drug products. As soon as feasible, submit (b) (4) each of STERITALC® (b) (4) STERITALC® (b) (4) and STERITALC® (b) (4) with Novatech S.A.'s TALCAIR® pulverization kit to the address below.

FDA Office of Testing and Research Laboratory
10903 New Hampshire Ave
Bldg # 64, Room 1036
Silver Spring, MD 20993
(ATTENTION: Akhtar Siddiqui, PhD)

Thank you for your prompt attention and assistance with this request,
Kristine

Kristine F. Leahy, RPh.
Regulatory Business and Process Manager
HHS | FDA | CDER
Office Of Pharmaceutical Quality (OPQ)
Office Of Program and Regulatory Operations (OPRO)
10903 New Hampshire Ave| WO75| Room 4623A|
Silver Spring, MD 20993
Ph: 240-402-5834
Kristine.leahy@fda.hhs.gov

This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at Kristine.leahy@fda.hhs.gov

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/s/

KRISTINE F LEAHY
07/26/2016

OKPONANABOFA ERADIRI
07/27/2016

From: Alebachew, Elleni
To: "Jennifer Neff"; smontgomery@bosmed.com
Bcc: Gao, Tingting
Subject: RE: NDA 205555 - Day 74 Letter
Date: Wednesday, July 27, 2016 10:39:00 AM

Hi Jennifer,

Please see below FDA's response in **Red**. This is in addition to the request from Kristine Leahy.

1) Is the FDA requesting an empty vial with the label or a vial including the talc which is also sterilized?

   Please send an empty vial with the label.

2) If we understand the request right, the FDA is requesting 3 samples in total (one sample each - (b) (4) (b) (4)

   Please send 3 representative samples total (one sample each for (b) (4) including vial, (b) (4) and carton, etc. in their representative packaging. Please ensure the representative samples are labeled with the proposed labeling (e.g. vial with the proposed container label instead of an unlabeled vial).

3) Is Novatech allowed to ship the vials, (b) (4) and cartons directly to the FDA or should our consulting company in (b) (4) as the legal representative submit this for us. Could you also inform us to whom we should send the samples, please? Is this you?

   Either Novatech or your consulting company can ship the items above. You can ship it to my attention. See address below.

   Elleni Alebachew
   Food and Drug Administration
   Center for Drug Evaluation and Research
   White Oak Building 22, Room: 2191
   10903 New Hampshire Avenue
   Silver Spring, Maryland
   Use zip code 20903 if shipping via United States Postal Service (USPS).
   Use zip code 20993 if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).

Regards,

Elleni Alebachew, MS, RAC
Senior Regulatory Health Project Manager
Division of Oncology Products 1
Office of Hematology and Oncology Products
FDA/ CDER/OND
E-mail: Elleni.Alebachew@fda.hhs.gov
Phone: (301) 796-5225
Fax: (301) 796-9845

From: Jennifer Neff [mailto:j.neff@bessgroup.com]
Sent: Tuesday, July 26, 2016 8:33 AM
To: Alebachew, Elleni; smontgomery@bosmed.com
Subject: AW: NDA 205555 - Day 74 Letter

Dear Elleni,
we are working on the requested documents and samples. However, the preparation of the following requests raises questions on our side:

We request that you submit the following information:
1. For the proposed container labels and carton labeling, please submit representative samples of a vial labeled with the proposed container label, and a carton labeled with the proposed carton labeling to aid in visualizing how the proposed product is packaged. Please clarify how the (b) (4) *will be packaged in the "carton label"*

1) Is the FDA requesting an empty vial with the label or a vial including the talc which is also sterilized?
2) If we understand the request right, the FDA is requesting 3 samples in total (one sample each - (b) (4)
3) Is Novatech allowed to ship the vials, (b) (4) (b) (4) and cartons directly to the FDA or should our consulting company in (b) (4) as the legal representative submit this for us. Could you also inform us to whom we should send the samples, please? Is this you?
   All other documents will be submitted electronically

I apologize for all these questions but we want to make sure that we submit correct samples and documents.

Kind regards,
Jennifer

Dr. Jennifer Neff, DVM, MBA, RAC
Director Regulatory & Medical Affairs

Tel. +49-30-816 909 817
Cell +49-162 21 21 217
Fax +49-30-816-909 816
on behalf of the bess group companies:
bess - Boston Medical Products - Novatech - Leufen
bess AG, Gustav-Krone-Strasse 7, DE-14167 Berlin
Legal venue: Berlin
Registered at Amtsgericht Berlin-Charlottenburg HRB 105 714
VAT D number: DE 252169351
Management board: Marcus A. Eisenhut (chairman), Gabriele Meissner, Chairman of the supervisory board: Dr. med. Corinna Eisenhut

---

Von: Alebachew, Elleni [mailto:Elleni.Alebachew@fda.hhs.gov]
Gesendet: Donnerstag, 23. Juni 2016 19:20
An: smontgomery@bosmed.com; Jennifer Neff <j.neff@bessgroup.com>
Betreff: NDA 205555 - Day 74 Letter

Hello,

Attached please find the Day 74 letter for NDA 205555.

Let me know if you have any questions.

Regards,

Elleni Alebachew, MS, RAC
Senior Regulatory Health Project Manager
Division of Oncology Products 1
Office of Hematology and Oncology Products
FDA/ CDER/OND
E-mail: Elleni.Alebachew@fda.hhs.gov
Phone: (301) 796-5225
Fax: (301) 796-9845

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/s/

ELLENI K ALEBACHEW
07/27/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

FILING COMMUNICATION –
NO FILING REVIEW ISSUES IDENTIFIED

Novatech S.A.
c/o Boston Medical Products Inc.
Attention: Stuart K. Montgomery
President
70 Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

Please refer to your New Drug Application (NDA) dated April 14, 2016, received April 14, 2016, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for STERITALC® (Talc) Powder, 2g, 3g, and 4g.

We also refer to your amendment dated June 14, 2016.

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 **February 14, 2017**.

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, mid-cycle, 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. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing commitment requests by **January 17, 2017.** This date conforms to the 21st Century Review timeline for your application. If our review continues on an expedited timeline, we may communicate revised dates for labeling and postmarketing requirement/commitment requests.

At this time, we are notifying you that, we have not identified any potential review issues. Please note that our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review.

We request that you submit the following information:

1. For the proposed container labels and carton labeling, please submit representative samples of a vial labeled with the proposed container label, and a carton labeled with the proposed carton labeling to aid in visualizing how the proposed product is packaged. Please clarify how the (b) (4) will be packaged in the "carton label".

PRESCRIBING INFORMATION

Your proposed prescribing information (PI) must conform to the content and format regulations found at 21 CFR 201.56(a) and (d) and 201.57. As you develop your proposed PI, we encourage you to review the labeling review resources on the *PLR Requirements for Prescribing Information* and *PLLR Requirements for Prescribing Information* websites including:

- The Final Rule (Physician Labeling Rule) on the content and format of the PI for human drug and biological products
- The Final Rule (Pregnancy and Lactation Labeling Rule) on the content and format of information in the PI on pregnancy, lactation, and females and males of reproductive potential
- Regulations and related guidance documents
- A sample tool illustrating the format for Highlights and Contents
- The Selected Requirements for Prescribing Information (SRPI) − a checklist of important format items from labeling regulations and guidances and
- FDA's established pharmacologic class (EPC) text phrases for inclusion in the Highlights Indications and Usage heading.

During our preliminary review of your submitted labeling, we have identified the following labeling issues and have the following labeling comments or questions:

1. Highlights (HL) should be in two-column format, with ½ inch margins on all sides and between columns.
2. The length of HL must be one-half page.
3. The preferred presentation for cross-references in the FPI is the section (not subsection) heading followed by the numerical identifier. The entire cross-reference should be in italics and enclosed within brackets. For example, *"[see Warnings and Precautions (5.2)]*."

We request that you resubmit labeling (in Microsoft Word format) that addresses these issues by August 23, 2016. The resubmitted labeling will be used for further labeling discussions. Use the SRPI checklist to correct any formatting errors to ensure conformance with the format items in regulations and guidances.

At the end of labeling discussions, use the SRPI checklist to ensure that the PI conforms with format items in regulations and guidances.

Please respond only to the above requests for 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.

PROMOTIONAL MATERIAL

You may request advisory comments on proposed introductory advertising and promotional labeling. Please submit, in triplicate, a detailed cover letter requesting advisory comments (list each proposed promotional piece in the cover letter along with the material type and material identification code, if applicable), the proposed promotional materials in draft or mock-up form with annotated references, and the proposed package insert (PI). Submit consumer-directed, professional-directed, and television advertisement materials separately and send each submission to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

Do not submit launch materials until you have received our proposed revisions to the package insert (PI), and you believe the labeling is close to the final version.

For more information regarding OPDP submissions, please see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm. If you have any questions, call OPDP at 301-796-1200.

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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because the drug product for this indication has orphan drug designation, you are exempt from this requirement.

If you have any questions, contact Elleni Alebachew, Regulatory Project Manager, at (301) 796-5225.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

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/s/

AMNA IBRAHIM
06/23/2016

From: Alebachew, Elleni
To: "j.neff@bessgroup.com"
Subject: NDA 205555 - FDA Communication: Request for Information
Date: Friday, May 13, 2016 12:07:00 PM
Importance: High

Hello,

Reference is made to your NDA resubmission received on April 14, 2016. Please respond to the information request below by **Friday, May 27, 2016.**

Based on our preliminary review, we have noted that there are differences in the indications for use for which the device (NOVATECH® TALCAIR™) is cleared and the indications for use you are requesting for the drug under the NDA 205555 (i.e., "For (b) (4) pneumothorax"). You should submit a 510(k) to include the added Indication you are requesting for the Drug (i.e., (b) (4) pneumothorax). You can either convert this submission into a combination product submission or revise the requested indication under the NDA to align it with the indications for use cleared under the 510(k) K151832.
Please contact CDRH for further discussion on the submission of a 510(k).

Regards,

Elleni Alebachew, MS, RAC
Senior Regulatory Health Project Manager
Division of Oncology Products 1
Office of Hematology and Oncology Products
FDA/ CDER/OND
E-mail: Elleni.Alebachew@fda.hhs.gov
Phone: (301) 796-5225
Fax: (301) 796-9845

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/s/

ELLENI K ALEBACHEW
05/13/2016

From: Alebachew, Elleni
To: "smontgomery@bosmed.com"
Subject: NDA 205555 - FDA Communication: Request for Information
Date: Wednesday, April 27, 2016 4:41:00 PM
Importance: High

Hello,

Reference is made to your NDA resubmission received on April 14, 2016. Please respond to the information request below by **Monday, May 2, 2016.**

> **In response to the RTF letter, you state, "this submission is only for the drug component." The following is from your proposed labeling (Section 2.3 and 3) " STERITALC® (b) (4) talc in glass vial, 3 g; to be used with Novatech S.A.'s TALCAIR® pulverization kit." In the submission, we cannot find more information for TALCAIR pulverization kit which appears to be a medical device. Please provide more information on the TALCAIR pulverization kit. If this has already been reviewed and cleared or approved by other centers (CDRH or CBER) of the FDA, please provide submission number (PMA or 510(k) notification) under which it is cleared/approved.**

Please confirm receipt.

Regards,

Elleni Alebachew, MS, RAC
Senior Regulatory Health Project Manager
Division of Oncology Products 1
Office of Hematology and Oncology Products
FDA/ CDER/OND
E-mail: Elleni.Alebachew@fda.hhs.gov
Phone: (301) 796-5225
Fax: (301) 796-9845

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/s/

ELLENI K ALEBACHEW
04/27/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205555

ACKNOWLEDGE RESUBMISSION
AFTER REFUSE-TO-FILE

Novatech S.A.
C/O Boston Medical Products Inc.
Attention: Stuart K. Montgomery
President
70Chestnut Street
Shrewsbury, MA 01545

Dear Mr. Montgomery:

We have received your new drug application (NDA) submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act in response to our May 3, 2013, refusal to file letter for the following:

Name of Drug Product:	STERITALC® (Talc), Powder, 2g, 3g, and 4g
Date of Application:	APRIL 14, 2016
Date of Receipt:	APRIL 14, 2016
Our Reference Number:	NDA 205555

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 June 13, 2016, 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.

You are also responsible for complying with the applicable provisions of sections 402(i) and 402(j) of the Public Health Service Act (PHS Act) [42 USC §§ 282 (i) and (j)], which was amended by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law No, 110-85, 121 Stat. 904).

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 Oncology Products 1
5901-B Ammendale Road
Beltsville, MD 20705-1266

Secure email between CDER and applicants is useful for informal communications when confidential information may be included in the message (for example, trade secrets or patient information). If you have not already established secure email with the FDA and would like to set it up, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications.

If you have any questions, call me, at (301) 796 5225.

Sincerely,

{See appended electronic signature page}

Elleni Alebachew, MS, RAC
Senior Regulatory Project Manager
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

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/s/

ELLENI K ALEBACHEW
04/20/2016