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RESEARCH**

*APPLICATION NUMBER:*  
**22-505**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

11-JUN-2010

**NDA 22-505/N-000**

**Drug Product Name**

**Proprietary:** Egrifta™

**Non-proprietary:** Tesamorelin acetate for injection

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

Submit	Received	Review Request	Assigned to Reviewer
22-MAY-2009	22-MAY-2009	N/A	22-JUN-2009

**Applicant/Sponsor**

**Name:** Theratechnologies, Inc.  
**Address:** 2310 Boulevard Alfred-Nobel  
Montreal (Quebec) Canada H4S 2B4  
**Representative:** Michelle Wilson, Ph.D.  
Senior Regulatory Consultant  
Kendle International  
**Telephone:** 513-829-1108

**Name of Reviewer:** Steven E. Fong, Ph.D.

**Conclusion:** CMC-Microbiology recommends APPROVE.

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## Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA.
  2. **SUBMISSION PROVIDES FOR:** New drug product.
  3. **MANUFACTURING SITE:**  
[REDACTED] (b) (4)
  4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
    - Sterile, lyophilized powder for injection.
    - Contents of two vials (2.2 mg total) reconstituted with 2.2 mL of sterile Water for Injection, USP (WFI, USP) prior to administration.
    - Subcutaneous administration route.
    - 2 mg dose given once-a-day.
  5. **METHOD(S) OF STERILIZATION:** [REDACTED] (b) (4) processing.
  6. **PHARMACOLOGICAL CATEGORY:** Lipodystrophy therapeutic.
- B. **SUPPORTING/RELATED DOCUMENTS:**
- DMF [REDACTED] (b) (4)
  - LOA dated 25-FEB-2009 permitting reference to DMF [REDACTED] (b) (4)
  - NDA 18-801.
  - LOA dated 27-MAR-2009 permitting reference to NDA 18-801.
  - 510K application [REDACTED] (b) (4) for 3 cc syringes fitted with 1-1/2" 18-gauge BD blunt fill needles.
  - 510K application [REDACTED] (b) (4) for 1-1/2" 18-gauge BD blunt fill needles.
  - [REDACTED] (b) (4)
  - 510K application [REDACTED] (u) (4) for 1/2" 27-gauge BD Eclipse™ needles.
- C. **REMARKS:**
- The submission was provided electronically in CTD format.
  - A LOA dated 10-JUL-2008 permitting reference to DMF [REDACTED] (b) (4) was provided in the application. An amendment providing a complete update to DMF [REDACTED] (b) (4) was submitted on 07-JUL-2008. In response to an 04-APR-2010 IR, an amendment update to the DMF was provided on 11-MAY-2010. The portions of the updated DMF relevant to this NDA were reviewed.
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- Validation of the process used to (b) (4) is presented in DMF (b) (4). A LOA dated 25-FEB-2009 permitting reference to DMF (b) (4) was provided with the application. The (b) (4) procedure was assessed in a 21-JAN-2009 microbiology quality review and found to be adequate.
  - (b) (4) sterilization of the sterile WFI, USP used as a product diluent is described in NDA 18-801. A LOA dated 27-MAR-2009 permitting reference to NDA 18-801 was provided with the application.
  - On 09-JUN-2010 an information request was sent to the sponsor regarding the syringe and needles proposed for product reconstitution and administration. The same day the sponsor provided an e-mail response that included the submission location of 510K clearance numbers for these items, and clarification about the number of items included in the product kit. The response stated that the sponsor would file a formal amendment with the information on 14-JUN-2010.

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22505	ORIG-1	THERATECHNOLOGIES INC	Egrifta

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/s/

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STEVEN E FONG

06/11/2010

Recommended for approval from a microbiology quality standpoint.

BRYAN S RILEY

06/11/2010

I concur.

# PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

**NDA Number: 22-505/N-000    Applicant: Thera Technologies Letter Date: 29-MAY-2009**

**Drug Name: Egrifta™                      NDA Type: Original NDA                      Stamp Date: 29-MAY-2009**  
**(tesamorelin acetate for injection)**

The following are necessary to initiate a review of the NDA application:

	<b>Content Parameter</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		Submission provided electronically in CTD format.
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		Sections 3.2.P.3.2 and 3.2.P.3.3
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		Section 3.2.P.3.5
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		X	Submission provided in English.
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		Product is provided as a sterile lyophilized powder that is reconstituted with sterile water and injected.
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		Sections 3.2.P.3.6.1 and 3.2.P.3.6.2.
7	Has the applicant submitted the results of analytical method verification studies?	X		Sections 3.2.P.3.5, 3.2.P.3.6.1., and 3.2.P.3.6.2.
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	N/A	N/A	Pre-submission microbiology quality requests were not made.
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The drug product is to be supplied as a lyophilized powder in a stoppered glass vial. The vial will be co-packaged in a kit that includes a diluent (WFI), disposable syringe, and disposable needle. Each 2 mg dose requires constitution of 2 vials of drug product with 2 vials of diluent. Immediately after reconstitution, the 1 mg/mL solution is to be administered subcutaneously. The sponsor was requested to provide a justification for why dosing is proposed with two vials containing 1 mg product each rather than a single vial containing 2 mg product.

Steven Fong, Ph.D.

24-JUL-2009

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Reviewing Microbiologist

Date

Stephen Langille, Ph.D.

24-JUL-2009

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Microbiology Secondary Reviewer/Senior Microbiologist

Date

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/s/  
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STEVEN E FONG  
09/28/2009

STEPHEN E LANGILLE  
09/28/2009