CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022523Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

17 NOVEMBER 2009

NDA: 22-523

Drug Product Name
Proprietary: PANCREAZE
Non-proprietary: pancrelipase microtablets

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
23 June 2009	23 June 2009	25 June 2009	25 June 2009

Submission History (for amendments only): N/A

Applicant/Sponsor
Name: Johnson and Johnson Pharmaceutical Research & Development, LLC
Address: 920 Route 202 South, Raritan, NJ 08869
Representative: Ilona Scott
Telephone: 908-927-3223

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original 505(b)(1)

2. SUBMISSION PROVIDES FOR: New Drug Product

3. MANUFACTURING SITE: Nordmark Arzneimittel GmbH & Co. KG
Pinnauallee 4
25436 Uetersen
Germany

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Non-sterile capsule for oral administration, 4200, 10500, 16800 and 21000 units of lipase

5. METHOD(S) OF STERILIZATION: N/A

6. PHARMACOLOGICAL CATEGORY: Treatment of (b) (4) exocrine pancreatic insufficiency.

B. SUPPORTING/RELATED DOCUMENTS: N/A

C. REMARKS: This was an eCTD submission.

filename: N022523R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – This submission is recommended for approval on the basis of product quality microbiology.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The drug product is a non-sterile capsule with microbial limits specifications.

B. Brief Description of Microbiology Deficiencies – N/A

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer's Signature _____
Bryan S. Riley, Ph.D.

B. Endorsement Block _____
James L. McVey, NDMS Team Leader

C. CC Block
N/A

4 Page(s) has (have) been Withheld in Full immediately following this page as B4 (CCI/ TS)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22523	ORIG-1	JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT LLC	Pancrelipase Microtablets

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/s/

BRYAN S RILEY
11/20/2009

JAMES L MCVEY
11/23/2009
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 22-523 **Applicant:** Johnson & Johnson **Letter Date:** 23 June 2009

Drug Name: PANCREASE MT **NDA Type:** 505(b)(1) **Stamp Date:** 23 June 2009

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

	Content Parameter	Yes	No	Comments
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		eCTD submission
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		
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	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		N/A
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		
7	Has the applicant submitted the results of analytical method verification studies?	X		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	X		
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The drug product is a non-sterile capsule filled with enteric-coated micro-tablets.

15 July 2009

Bryan S. Riley, Ph.D. Date
Senior Review Microbiologist

James L. McVey Date
OPS/NDMS Team Leader

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/s/

Bryan Riley
7/20/2009 10:58:28 AM
MICROBIOLOGIST

James McVey
7/20/2009 11:43:27 AM
MICROBIOLOGIST
I concur.