CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205919Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 03 April 2014

TO: NDA 205-919

FROM: Jessica G. Cole, PhD
Review Microbiologist
CDER/OPS/New Drug Microbiology Staff
(301) 796-5148

THROUGH: Bryan Riley
Microbiology Team Leader
CDER/OPS/New Drug Microbiology Staff

cc: Kristopher Kolibab
Regulatory Health Project Manager
CDER/OND/OHOP/DHP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for Purixan (Mercaptopurine) Oral Solution [Submission Date: 10 July 2013]

The Microbial Limits specification for Purixan (Mercaptopurine) Oral Solution is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

Purixan (Mercaptopurine) is a preserved, non-sterile solution for oral administration submitted by Nova Laboratories, Ltd. The product is intended to treat children, adults, and adolescents with acute lymphoblastic leukemia. This is a 505(b)(2) NDA with Orphan Designation and the referenced listed drug is NDA 009-053.

The 20 mg/mL drug product is formulated with sterile, purified water and is (b) (4) See below for information on the (b) (4) studies conducted during development. The drug product is tested for Microbial Limits at release using a method consistent with USP Chapter <61> (Microbiological Examination of Non-sterile Products: Microbial Enumeration Tests) and <62> (Microbiological Examination of Non-sterile Products: Tests for Specified Microorganisms). The Microbial Limits acceptance criteria are consistent with USP Chapter <1111> (Microbiological Examination of Non-sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for

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(b) (4)

(b) (4)

ADEQUATE

Reviewer Comment – The microbiological quality of the drug product is adequately controlled.

END

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/s/

JESSICA COLE
04/03/2014

BRYAN S RILEY
04/03/2014
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 205-919 **Applicant:** Nova Laboratories Inc. **Letter Date:** 09 July 2013

Drug Name: (b) (4) (mercaptopurine) oral suspension **NDA Type:** 505(b)(2) **Stamp Date:** 10 July 2013

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		
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		
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?			Not applicable
9	If sterile, are extended post-constitution and/or post-dilution hold times in the draft labeling supported by microbiological data?			Not applicable
10	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: This is a non-sterile, (b) (4) aqueous oral suspension product. There are microbial limits for the drug product but no release test is proposed for the *Burkholderia cepacia* complex (BCC). BCC are capable of growth in preserved drug products and at pH<4.0.

The following information request should be sent to the applicant in the filing communication.

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	8/2/13
Jessica G. Cole, PhD Review Microbiologist	Date
Bryan Riley, PhD Microbiology Team Leader	Date

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/s/

JESSICA COLE
08/26/2013

BRYAN S RILEY
08/26/2013
I concur.