CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207620Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)





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

DATE: 03 February 2015

TO: NDA 207620

Robert J. Mello, Ph.D. FROM:

Senior Review Microbiologist

CDER/OPQ/OPF/DMA

THROUGH: Neal J. Sweeney, Ph.D.

Senior Review Microbiologist

CDER/OPQ/OPF/DMA

Olga Simakova cc:

Regulatory Health Project Manager

CDER/OPQ/OPRO

SUBJECT: Filing Review and Product Quality Microbiology assessment of

Microbial Limits for LCZ696 (sacubitril/valsartan) 50mg, 100mg and

200mg film coated tablets [Submission Date: 09 September 2014].

Description: The drug product, LCZ696 (sacubitril/valsartan) 50 mg, 100 mg, 200 mg film-coated tablet is an immediate release dosage form for oral administration. The 50mg dosage form is a violet white, ovaloid, biconvex film-coated tablet with beveled edges, unscored, debossed with "NVR" on one side and "LZ" on the other side. The 100mg dosage form is a pale yellow, ovaloid, biconvex filmcoated tablet with beveled edges, unscored, debossed with "NVR" on one side and "L1" on the other side. The 200mg dosage form is a light pink, ovaloid, biconvex film-coated tablet with beveled edges, unscored, debossed with "NVR" on one side and "L11" on the other side. All three dosage forms will be produced at the Novartis Stein Switzerland Facility.

It is noted here that the NDA contains a comparability protocol	for the post approval	(D) (4)
	. There are no micro	obiology review
issues to address in the comparability protocol.		

The description of the manufacturing process indicates that the

(b) (4)

Composition: The composition of the core is shown in Table 2-1, below (copied from submission



Endorsement page:

Robert J. Mello, Ph.D. Senior Microbiology Reviewer OPQ/OPF/DMA

Neal J. Sweeney, Ph.D. Senior Microbiology Reviewer OPQ/OPF/DMA



Neal J.

Digitally signed by Neal J.
Sweeney -A
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
0.9,2342.19200300.100.1.1=13001
09587, cn=Neal J. Sweeney -A
Date: 2015.02.05 14:58:04-05'00'

