# 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

**FROM:** Robert J. Mello, Ph.D.
Senior Review Microbiologist
CDER/OPQ/OPF/DMA

**THROUGH:** Neal J. Sweeney, Ph.D.
Senior Review Microbiologist
CDER/OPQ/OPF/DMA

**cc:** Olga Simakova
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 film-coated 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 (b) (4) . There are no microbiology review issues to address in the comparability protocol.

The description of the manufacturing process indicates that the (b) (4) (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

Robert J. Mello -A
Digitally signed by Robert J. Mello -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300369984, cn=Robert J. Mello -A
Date: 2015.02.05 14:53:08 -05'00'

Neal J. Sweeney, Ph.D.
Senior Microbiology Reviewer
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