APPLICATION NUMBER:

207620Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)
DATE: 03 February 2015
TO: NDA 207620
FROM: Robert J. Mello, Ph.D.
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cc: Olga Simakova
Regulatory Health Project Manager
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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
issues to address in the comparability protocol.

The description of the manufacturing process indicates that the

Composition: The composition of the core is shown in Table 2-1, below (copied from submission section 3.2.P.1, pages 3-4/4; highlighted portion added by reviewer).

2 Pages Have Been Withheld In Full As b4 (CCI/TS) Immediately Following This Page
Endorsement page:

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