CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205060Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)
DATE: 19 July 2013

TO: NDA 205060

FROM: Bryan S. Riley, Ph.D.
Team Leader (Acting)
OPS/New Drug Microbiology Staff

THROUGH: Stephen E. Langille, Ph.D.
Senior Review Microbiologist
OPS/New Drug Microbiology Staff

cc: Kati Johnson
Senior Regulatory Project Manager
OND/DMEP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for Epanova™ Capsules [Submission Date: 3 July 2013]

The Microbial Limits specification for Epanova Capsules is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

Epanova™ is a Capsule" for oral administration.

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 Pharmaceutical Use).

Reference ID: 3343919
MEMORANDUM

Table 1 – Microbial Limits Specification

<table>
<thead>
<tr>
<th>Test</th>
<th>Acceptance Criteria</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Aerobic Microbial Count</td>
<td>NMT CFU/g</td>
<td>HMR/2K/M57 (EP 2.6.12)</td>
</tr>
<tr>
<td>Total Yeast and Mold Count</td>
<td>NMT CFU/g</td>
<td>HMR/2K/M58 (EP 2.6.13)</td>
</tr>
<tr>
<td><em>E. coli</em></td>
<td>Absent/g</td>
<td></td>
</tr>
<tr>
<td><em>Salmonella</em></td>
<td>Absent/g</td>
<td></td>
</tr>
</tbody>
</table>

The Microbial Limits test methods were verified to be appropriate for use with the drug product following procedures consistent with those in USP Chapter <61> and <62>.

The drug product will also be tested for Microbial Limits annually as part of the post-approval stability protocol.

ADEQUATE

Reviewer Comments – The microbiological quality of the drug product is controlled via a suitable testing protocol. The test methods used are the microbial limits chapters in the European Pharmacopeia which have been harmonized with USP Chapters <61> and <62>.

END
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/s/

BRYAN S RILEY  
07/19/2013

STEPHEN E LANGILLE  
07/19/2013