<table>
<thead>
<tr>
<th><strong>Sample Class:</strong></th>
<th>Quality Assurance</th>
<th><strong>Sample Origin:</strong></th>
<th>Domestic</th>
<th><strong>Sample Basis:</strong></th>
<th>Compliance</th>
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<tbody>
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<td><strong>Sample Flag:</strong></td>
<td></td>
<td><strong>Sample Type:</strong></td>
<td>Investigational</td>
<td><strong>Collecting District:</strong></td>
<td>PHRM2</td>
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<td><strong>Home District:</strong></td>
<td></td>
<td><strong>Orig C/R and Records To:</strong></td>
<td>FLA-DO</td>
<td><strong>Collection PACs:</strong></td>
<td>56D017</td>
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</tbody>
</table>

**Product Name:** Miscellaneous Patent Medicines, Etc.; Human - Rx/Single Ingredient; Active Pharm Ingred/Chems for Rx

**Product Description:** Environmental Sampling (plates, swabs, sponges, material)

**Collection Reason:** CDER directed sample collection initiated during EI at Pacifico National, Inc. dba AmEx Pharmacy; Please analyze for sterility.
Lab: NMPL  Split Num: 0  Date Received: 05/04/2019  Date Out of Lab: 07/05/2019

District Conclusion:

Disposition Reason:

Disposition Made By:

Disposition Authorized By:

Lab Class-Description: 4 - No Classification Required  Laboratory Status: Completed

Lab Conclusion

One (1) fungal isolate sequenced:
Sub 68 6/14/19 SH: Most homologous to Hamigera avellanea, H. insecticola and H. paravellanea;

Six (6) bacterial isolates sequenced:
Sub 75 BAP 5-10: Most homologous to Paenibacillus spp.;
Sub 79 MLA 5-7: Most homologous to Staphylococcus hominis novobiosepticus and S. hominis hominis;
Sub 79 SDA 5-7: Most homologous to Staphylococcus hominis novobiosepticus and S. hominis hominis;
Sub 79 MLA 5-10: Most homologous to Staphylococcus hominis novobiosepticus and S. hominis hominis;
Sub 79 MLA 5-18: Most homologous to Staphylococcus hominis novobiosepticus and S. hominis hominis;
Sub 89 BAP 5-18: Most homologous to Cohnella spp.

All controls were satisfactory.

Lab Conclusion Date  Lab Conclusion Made By
07/05/2019 Silverman, Matthew D

Performing Org  PAC  LID  PAF  Compliance No  Lab Class-Description  Laboratory Status
NMPL-LAB-G  56D017  NAR  3  - Adverse Findings  Completed

Lab Conclusion

Growth was detected in subs 68, 75, 77, 79, 81 and 89.
1.0 CFU was detected on RODAC sub no. 68. Isolate sent to WEAC for further fungal identification.
Paenibacillus glucanolyticus,(Bacillus circulans), Paenibacillus lautus, and Bacillus megaterium were isolated from sub 75. In addition, one isolate sent to WEAC for further bacterial identification from Sub 75.
Staphylococcus haemolyticus, Staphylococcus hominis ssp. hominis, Staphylococcus epidermidis and Staphylococcus warneri were isolated from Sub 77.
Staphylococcus epidermidis and Staphylococcus hominis ssp. hominis, were isolated from Sub 79. In addition, four isolates sent to WEAC for further bacterial identification from Sub 79.
Micrococcus luteus was isolated from sub 81, and Paenibacillus macerans was isolated from sub 89. In addition, one isolate sent to WEAC for further bacterial identification from Sub 89.
No growth was detected in subs no. 1-67, 69-74, 76, 78, 80, 82-88 & 90-105 after 14 days of incubation.
Collector's controls: A, B, C, D, E F and G were negative for growth after 14 days of incubation.
All controls gave valid results.

Lab Conclusion Date  Lab Conclusion Made By
06/20/2019 Romero, Haydee B

Date: 08/02/2019