**Agenda Notes for discussion in the 8th (2017-2018) Meeting of the Unit Approval Committee to be held on 15.12.2017 at 1100 Hrs in the Conference Room of M/s. DLF Commercial Developers Limited Special Economic Zone, Gachibowli Village, Serilingampally Mandal, Hyderabad.**

**Visakhapatnam Special Economic Zone**

<table>
<thead>
<tr>
<th>Agenda Item No.</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item No. 1</td>
<td>Ratification of the Minutes of the Meeting of the Unit Approval Committee held on 17.10.2017</td>
<td>2</td>
</tr>
<tr>
<td>Agenda Item No. 2</td>
<td>Action taken report for the Meeting of the Unit Approval Committee held on 17.10.2017</td>
<td>3</td>
</tr>
<tr>
<td>Agenda Item No. 3</td>
<td>Proposal of M/s. Graviti Pharmaceuticals Pvt. Ltd, 100% EOU for extension of validity of their LOP dated 26.10.2014.</td>
<td>4 to 5</td>
</tr>
</tbody>
</table>
Agenda Item No. 1: Ratification of the Minutes of the Meeting of the Unit Approval Committee held on 17.10.2017.

The minutes of the meeting are enclosed herewith. The Committee is requested to ratify the same.
Agenda Item No. 2: Action taken report of 6th (2017-2018) of the Unit Approval Committee held on 17.10.2017 at 1500 Hrs in the Conference Room of M/s. DLF Commercial Developers Pvt. Limited Special Economic Zone, Gachibowli, Hyderabad.

The Action Taken on the decisions taken in the previous meeting of the UAC for EOUs is submitted hereunder for information of UAC:

<table>
<thead>
<tr>
<th>Agenda Item No.</th>
<th>Decision of the UAC</th>
<th>Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item No. 3</td>
<td>Proposal of M/s. Jatinn Exports for setting up of 100% EOU for manufacture and export of “Processing of Gherkins in Natural Vinegar, Brine, Acetic Acid in Bulk” at Sy. No. 60/A, Kottapally Village, Midjil Mandal, Mahaboobnagar District, Telangana</td>
<td>Approval conveyed</td>
</tr>
<tr>
<td>Agenda Item No. 4</td>
<td>Proposal of M/s. Valeth Hightech Composites Pvt. Ltd for setting up of 100% EOU for manufacture and export of ‘Spike-MR ATGM Ganister’ at Plot No. 3/5/C, Sy. No. 255, Hardware Part Expn IT/ITES, Adibatla Village, Ibrahimpatnam Mandal, Ranga Reddy District, Telangana</td>
<td>Approval conveyed</td>
</tr>
<tr>
<td>Agenda Item No. 5</td>
<td>Proposal of M/s. Airis Pharma Pvt. Ltd, 100% EOU for extension of validity of their LOP dated 25.7.2014.</td>
<td>Approval conveyed</td>
</tr>
</tbody>
</table>

M/s. Graviti Pharmaceuticals Pvt. Ltd was issued LOP No. 104/EOU/VSEZ/HYD/2014 dated 27.10.2014 for setting up 100% EOU for manufacture and export of “Pharmaceutical Formulations” at Sy. No. 621, Isnapur Village, Patancheru Mandal, Medak District, Telangana. The unit had not commenced operations as on date. The LOP is valid upto 26.10.2017.

Now, the unit vide its letter dated 20.11.2017 has stated that their project has been progressed considerably. The same has been reviewed by lender engineer during the periodic inspections carried out by him and the copy of the report certifying the work in progress on quarterly basis.

The unit has also stated that the Business Plan has three crucial elements namely:

1) Molecule development
2) FDA filing and approval
3) Manufacturing roll-out and commercialization

**Status on Molecule Development:** The progress of the molecule development is as per scheduled plan and periodic updates are being provided on the same as per the terms of LOP.

**Status on the FDA filing and approval:** They filed seven molecules with the USFDA upto 30.9.2017 and they have got USFDA facility approval for plant. The processing of their filings and issuing an approval is expected to take at least 12 to 15 months from the date of filing. They have reasons to believe that the approval timeline may even extend beyond this timeline. Hence, their opportunity to commercialize drugs may be delayed beyond the original expected timelines by 0-12 months.

**Status on Manufacturing roll-out and commercialization:** The manufacturing facility has been planned to roll out based on the USFDA facility approval received. They filed seven molecules with the USFDA. Product approval will be received within expected timeline of 8 months from the letter date.

In view of the above submissions, they expect their commercial production of the project would be sometime in early December, 2018 as against the committed time frame of April, 2017 in the project report.

Considering the size of the project, nature of the project and complexities involved in the project, they are sure that they shall appreciate their concerns and agree on the timelines. Hence, the unit has requested to amend the project sanction terms and conditions and provide relaxation in timelines accordingly.

The unit has also stated that they are procuring capital goods, consumables, packing materials and raw materials for exhibit batch, as per the QPRs declared date of commencement of production will be on 01.04.2018 instead of 01.04.2017.

The unit has also submitted a report on their EOU unit for the period ending 30.9.2017.

The unit has submitted Chartered Engineer’s certificate stating that they had completed 64% in physical progress of the project and spent Rs. 127.47 Crores on Land, Building and Civil works etc as on 24.9.2017.
M/s. Graviti Pharmaceuticals Pvt. Ltd has requested this office to extend their LOP upto 2 years at the earliest.

In terms of Para 6.05 (a) of FTP, 2015-20 which states that “On approval, a Letter of Permission (LoP) / Letter of Intent (LoI) shall be issued by DC / designated officer to EOU/ EHTP / STP / BTP unit. LoP / LoI shall have an initial validity of 2 years to enable the Unit to construct the plant & install the machinery and by this time the unit should have commenced production. In case the unit is not able to commence production in initial validity of 2 years, an extension of one year may be given by the DC for valid reasons to be recorded in writing. Subsequent extension of one year may be given by the Unit Approval Committee subject to condition that two-thirds of activities including construction, relating to the setting up of the Unit are complete and Chartered Engineer’s certificate to this effect is submitted by the Unit. Further extension, if necessary, will be granted by the Board of Approval. Once unit commences production, LoP / LoI issued shall be valid for a period of 5 years for its activities. This period may be extended further by DC for a period of 5 years at a time”.

The proposal of the unit is placed before UAC for approval please.

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