

**TABLE AGENDA FOR 111<sup>th</sup> UNIT APPROVAL COMMITTEEs MEETING FOR THE SEZs LOCATED IN VSEZ & OTHER PRIVATE SEZs OF ANDHRA PRADESH REGION TO BE HELD ON 29.11.2019 AT 11.00 A.M. AT CONFERENCE HALL, ADMINISTRATIVE BUILDING, VISAKHAPATNAM SPECIAL ECONOMIC ZONE, DUVVADA, VISAKHAPATNAM.**

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**TABLE AGENDA**

**Table Agenda Item No. 01:- Dr. Reddy's Laboratories Ltd, FTO, SEZ Process unit-01, a unit in Ranastalam Mandal, Srikakulam for inclusion of additional products in the existing LoA.**

Dr. Reddy's Laboratories Ltd, FTO, SEZ Process unit-01, Sector specific SEZ located in Ranastalam Mandal, Srikakulam has requested for inclusion of following additional products in the existing LoA:-

| Sl. No. | Item of manufacture                        | Tablets/<br>Capsules | ITC HS code | Projected annual Capacity | Projected annual exports |
|---------|--|----------------------|-------------|---------------------------|--------------------------|
| 1       | Tofacitinib Extended Release Tablets 11 mg | Tablets              | 30049099    | 15,00,000 Nos.            | 68.72 crores             |

The unit has declared that the export/import of the products are not in the restricted/prohibited list of goods in terms of ITC(HS).

In this regard, the unit has submitted drug licenses vide No.L.Dis.No. 4801/P&B/2019 dt.18.10.2019 which is valid upto 17.10.2022.

In terms of Rule 19(2), approval Committee may also approve proposal for broad banding diversification, enhancement of capacity of production, change in the terms of manufacture or service activity..

Accordingly, the proposal is placed before UAC for consideration

**Table Agenda Item No. 02: Dr. Reddy's Laboratories Ltd, FTO, SEZ Process unit-02, a unit in Ranastalam Mandal, Srikakulam for inclusion of additional products in the existing LoA.**

Dr. Reddy's Laboratories Ltd, FTO, SEZ Process unit-02, Sector specific SEZ located in Ranastalam Mandal, Srikakulam has requested for inclusion of following additional products in the existing LoA:-

| Sl. No. | Item of manufacture           | Capsules/Tablets/<br>pellets/Inhalation<br>aerosol /<br>Granules /<br>Sachets / Spray /<br>Spray/capsules /<br>tubes / Oral<br>Suspension /<br>Lotion | ITC HS code | Projected annual Capacity | Projected annual exports |
|---------|-------------------------------|---|-------------|---------------------------|--------------------------|
| 1       | Sucralfate Suspension 1g/10ml | Ointment  | 30049099    | 6300 Nos.<br>(Bottles)    | 7.02 Crs.                |

The unit has enclosed drug licenses vide No. L. Dis. No. 4121/P&B/2019 dt.11.09.2019 which shall be in force for three years from the date of issue.

In terms of Rule 19(2), approval Committee may also approve proposal for broad banding diversification, enhancement of capacity of production, change in the terms of manufacture or service activity..

Accordingly, the proposal is placed before UAC for consideration.

**Table Agenda Item No. 03: M/s.GVK Biosciences Private Limited, a unit in Ramky Pharma SEZ, Parawada, Visakhapatnam for inclusion of additional products in the LoA.**

M/s.GVK Biosciences Private Limited a unit in Ramky Pharma SEZ, Parawada, has requested for inclusion of following additional products in the existing LoA:-

| S. No | Name of the Intermediate Product   | Project code | HSN Code    | Annual Capacity |
|-------|--|--------------|-------------|-----------------|
| 1     | N-(2-chloropyridin-3-yl)-2-nitrobenzamide(stage-1)(CDS-0188)                           | CDS-0188     | 2933.99.090 | 100 KG          |
| 2     | 2-amino-N-(2-chloropyridin-3-yl)benzamide(stage-2)(CDS-0188)                           | CDS-0188     | 2933.99.090 | 100 KG          |
| 3     | 5,11-dihydro-6H-benzo[e]pyrido[3,2-b][1,4]diazepin-6-one (OS24301)(stage-3) (CDS-0188) | CDS-0188     | 2933.99.090 | 1000 KG         |

As per the application it is observed that the unit has not furnished the drug license for the said products, since the above products are intermediates.

In terms of Rule 19(2), approval Committee may also approve proposal for broad banding diversification, enhancement of capacity of production, change in the terms of manufacture or service activity.

Accordingly, the proposal is placed before UAC for consideration.

**Table Agenda Item No. 04: M/s.GVK Biosciences Private Limited, a unit in Ramky Pharma SEZ, Parawada, Visakhapatnam for Product Name Change in LOA.**

M/s. GVK Biosciences Private Limited vide letter dated 11.11.2019 has informed that there is been typo error in chemical name when applying for approval which was approved on 15.10.2019 as detailed below:-

| LoA Chemical Name   | Required chemical Name   |
|---|--|
| (R)-N-ethyl-N-(piperidin-2-ylmethyl)ethanamine hydrochloride salt (CDS-175) (OS24303) | (R)-N-ethyl-N-(piperidin-2-ylmethyl)ethanamine dihydrochloride |

The unit has informed that there is no change in HSN code and requested to change the chemical name as per they required.

In this regard it is to submit that the above product was approved in the Unit Approval Committee in its meeting held on 25.09.2019 and conveyed to the unit vide this office letter dated. 15.10.2019 at Sl. No. 4.

The request of the unit for change the chemical name has been approved vide this office letter dated. 20.11.2019.

The approval for change the chemical name is placed before UAC for ratification.

**Table Agenda Item No. 05:- Dr. Reddy's Laboratories Ltd, CTO, SEZ Process unit-01, a unit in Ranastalam Mandal, Srikakulam for inclusion of additional products in the existing LoA.**

Dr. Reddy's Laboratories Ltd, CTO, SEZ Process unit-01, Sector specific SEZ located in Ranastalam Mandal, Srikakulam has requested for inclusion of following additional products in the existing LoA:-

| Sl. No. | Item of manufacture   | API/Intermediate | ITC HS code | Projected annual Capacity | Projected annual exports |
|---------|---|------------------|-------------|---------------------------|--------------------------|
| 1       | 4-methyl-7(((2R,3R,4R,4S,5S)3,4,5-trihydroxytetrahydro-2H-thiopyran-2yl)oxy)2H-chromen-2-one or Odiparcil or CTEU3 Micronised | API/Intermediate | 29349990    | 220 Kgs.                  | 8.80 crores              |

The unit has declared that the export/import of the products are not in the restricted/prohibited list of goods in terms of ITC(HS).

In this regard, the unit has submitted drug licenses vide No.L.Dis.No. 4347/P&B/2019 dt.11.09.2019 and 147/P&B/2019 dt.23.01.2019 which are valid upto 30.06.2023.

In terms of Rule 19(2), approval Committee may also approve proposal for broad banding diversification, enhancement of capacity of production, change in the terms of manufacture or service activity..

Accordingly, the proposal is placed before UAC for consideration.

**Table Agenda Item No.06: M/s.Divi's Laboratories Limited (DSN SEZ unit) a unit in M/s. Divi's Laboratories Limited SEZ, Chippada Vill, Bheemunipatnm, Visakhapatnam for permission to include of 'Disposal of Waste Service' in the approved list of Services – Reg.**

M/s. Divi's Laboratories Limited-DSN SEZ Unit vide letter dated. 18.11.2019 has informed that during the manufacturing process certain waste/spent chemicals will generate and they are disposing the mixed spent solvents in DTA on payment of applicable duties and some of them they are neutralizing as per the norms and discharging through drains. But, due to some process change some of the Waste / spent chemicals generated in the manufacturing process cannot be sold or can neither be neutralized in their facility, as such they have decided to send them to approved treatment facilities like Treatment of Solid Disposal facility at Ramky, Parawada which is approved by MOEF for treatment and disposal by obtaining all the necessary approvals from the authorities.

In view of the above, the unit has requested for inclusion of additional service i.e. "Disposal of Waste Service" in the list of Services.

It is inform that DoC has approved 67 services which may be permitted by all the UACs as default authorized services, it is observed that in the Uniform List of Services, the above service i.e., "Disposal of Waste Service" is not listed. The services which are not listed in the Uniform List may be decided by the UAC on merit.

Accordingly, the proposal is placed before UAC for consideration

**Table Agenda Item No.07: M/s.Divi's Laboratories Limited (SEZ unit) a unit in M/s. Divi's Laboratories Limited SEZ, Chippada Vill, Bheemunipatnm, Visakhapatnam for permission to include of 'Disposal of Waste Service' in the approved list of Services – Reg.**

M/s. Divi's Laboratories Limited- SEZ Unit vide letter dated. 18.11.2019 has informed that during the manufacturing process certain waste/spent chemicals will generate and they are disposing the mixed spent solvents in DTA on payment of applicable duties and some of them they are neutralizing as per the norms and discharging through drains. But, due to some process change some of the Waste / spent chemicals generated in the manufacturing process cannot be sold or can neither be neutralized in their facility, as such they have decided to send them to approved treatment facilities like Treatment of Solid Disposal facility at Ramky, Parawada which is approved by MOEF for treatment and disposal by obtaining all the necessary approvals from the authorities.

In view of the above, the unit has requested for inclusion of additional service i.e. "Disposal of Waste Service" in the list of Services.

It is inform that DoC has approved 67 services which may be permitted by all the UACs as default authorized services, it is observed that in the Uniform List of Services, the above service i.e., "Disposal of Waste Service" is not listed. The services which are not listed in the Uniform List may be decided by the UAC on merit.

Accordingly, the proposal is placed before UAC for consideration

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