

TABLE AGENDA-2 FOR 116th UNIT APPROVAL COMMITTEES MEETING FOR THE PRIVATE SEZs OF ANDHRA PRADESH REGION TO BE HELD ON 26.06.2020 AT 11.00 A.M. AT CONFERENCE HALL, ADMINISTRATIVE BUILDING, VISAKHAPATNAM SPECIAL ECONOMIC ZONE, DUVVADA, VISAKHAPATNAM.

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TABLE AGENDA - 2

Table Agenda Item No. 01 : Request for permission to enhance the limit of HSD procurement to 1000 KL from the existing 400 KL without payment of duty for authorized operations for one year–Dr. Reddy’s Lab Ltd, SEZ Developer- Reg.

Dr. Reddy’s Lab Ltd, SEZ Developer vide letter dated 15.06.2020 has requested for permission to enhance the limit of HSD procurement to 800 KL from the existing 400 KL for procurement of HSD for a period of one year. The Developer has been granted permission for procurement of HSD for a quantity of 400 KL for one year vide this office letter dated 06.02.2019. Now the developer has informed that the consumption on monthly basis is increasing on an average i.e. 60 KL and the permission granted for 400 KL is almost exhausted. The Developer has submitted details of the procurement and consumption.

The Developer has submitted the HSD requirement duly certified by the Chartered Engineer.

In terms of SEZ Rules 2006, Rule 12 (2). for Import and procurement of goods by the Developer:“The Developer shall make an application, after obtaining approval for the authorized operation under rule 9, to the Development Commissioner, along with the list of goods and services, including machinery, equipment and construction materials required for the authorized operations, duly certified by a Chartered Engineer for approval by the Approval Committee.”

Accordingly, the proposal is placed before UAC for consideration.

Table Agenda Item No.02:- Request of M/s. Dr. Reddy’s Lab Ltd, CTO SEZ Process Unit-01, unit in Dr. Reddy’s Lab Ltd SEZ for inclusion of additional product under broad-banding in LOA.

M/s. Dr. Reddy’s Lab Ltd, CTO SEZ unit -01 vide letters dated 19.06.2020 has requested for inclusion of the following additional products in the LoA..

S.No	Name of the Product	APIs/Intermediate s/Bulk Drugs	ITC CODE NO.	Annual Capacity	Projecte d annual exports
1	Remdesivir	APIs /Intermediates/	29331999	24.00 Kg.	20.10 crores

The unit has informed that they have been regularly including new products for manufacture in the LoA in addition to the products already included.

Further, as the facility is established for manufacture of Tablets and Capsuls, they shall manufacture the respective products basing on the orders received. This is a continuous process.

The capacity and project exports due to addition of the above products in LoA for manufacture are already part of their projection given at the time of submission of application. As indicated below, the name of the product may vary from time to time depending on the market conditions.

In the present cases, the drug license is for Testing purpose and hence, there will be no commercial sale of the product until the same is commercialized. They are theregore giving the proposed capacity and approx..value of the product which will be part of the existing capacity.

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. Sp1114/P&B/2020, dt.26.05.2020 which are valid upto 25.05.2023.

The unit has not furnished NFE projection of the above product.

In terms of Rule 19(2), approval Committee may also approve proposal for broad banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity, if it meets the requirement of rules 18.

Accordingly, the proposal is placed before UAC for consideration.

Table Agenda Item No. 03:- Request of M/s. Dr. Reddy's Lab Ltd, FTO SEZ Process Unit-01, unit in Dr. Reddy's Lab Ltd SEZ for inclusion of additional product under broad-banding in LOA.

M/s. Dr.Reddy's Lab Ltd, FTO SEZ unit -01 vide letters dated 17.06.2020 has requested for inclusion of the following additional products in the LoA..

S.No	Name of the Product	Capsule/Tablet/pellets/inhalation/Aerosol/Granules/Sachets/Spray/Capsules	ITC CODE NO.	Projected Qty	Approx value of the goods (Rs.in lakhs)
1	Propranolol Hydrochloride Tablets USP 10 mg	Tablets	30049099	1000000 Nos	6.50
2	Propranolol Hydrochloride Tablets USP 20 mg	Tablets	30049099	1000000 Nos	7.40
3	Propranolol Hydrochloride Tablets USP 40 mg	Tablets	30049099	1000000 Nos	9.10
4	Propranolol Hydrochloride Tablets USP 60 mg	Tablets	30049099	1000000 Nos	10.70
5	Propranolol Hydrochloride Tablets USP 80 mg	Tablets	30049099	1000000 Nos	12.00

The unit has informed that they have been regularly including new products for manufacture in the LoA in addition to the products already included.

Further, as the facility is established for manufacture of Tablets and Capsuls, they shall manufacture the respective products basing on the orders received. This is a continuous process.

The capacity and project exports due to addition of the above products in LoA for manufacture are already part of their projection given at the time of submission of application. As indicated below, the name of the product may vary from time to time depending on the market conditions.

In the present cases, the drug license is for Testing purpose and hence, there will be no commercial sale of the product until the same is commercialized. They are therefore giving the proposed capacity and approx..value of the product which will be part of the existing capacity.

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 Nos. HMF07-14051/39/2020-TECH-DCA & HMF07-14051/41/2020-TECH-DCA dt.12.06.2020 which are valid upto 11.06.2023.

The unit has not furnished NFE projection of the above product.

In terms of Rule 19(2), approval Committee may also approve proposal for broad banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity, if it meets the requirement of rules 18.

Accordingly, the proposal is placed before UAC for consideration.

Table Agenda Item No. 04:- Request of M/s. Dr. Reddy's Lab Ltd, FTO SEZ Process Unit-02, unit in Dr. Reddy's Lab Ltd SEZ for inclusion of additional product under broad-banding in LOA.

M/s. Dr. Reddy's Lab Ltd, FTO SEZ unit -02 vide letters dated 17.06.2020 has requested for inclusion of the following additional products in the LoA..

S.No	Name of the Product	Capsule/Tablet/pellets/ inhalation/Aerosol/Gra nules/Sachets/Spray/ Cream Tubes/Oral Suspension /Lotion	ITC CODE NO.	Projected Qty	Approx value of the goods (Rs.in lakhs)
1	Dexpanthenol and Allantoin Cream (5% +0.5%) w/w Dexpan Plus Cream 30g 50g	Cream	30049099	41665 Nos. 25000 Nos.	43.23 41.50

The unit has informed that they have been regularly including new products for manufacture in the LoA in addition to the products already included.

Further, as the facility is established for manufacture of Tablets and Capsules, they shall manufacture the respective products basing on the orders received. This is a continuous process.

The capacity and project exports due to addition of the above products in LoA for manufacture are already part of their projection given at the time of submission of application. As indicated below, the name of the product may vary from time to time depending on the market conditions.

In the present cases, the drug license is for Testing purpose and hence, there will be no commercial sale of the product until the same is commercialized. They are therefore giving the proposed capacity and approx..value of the product which will be part of the existing capacity.

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. HMF07-14051/44/2020-TECH-DCA dt.12.06.2020 which is valid upto 11.06.2023.

The unit has not furnished NFE projection of the above product.

In terms of Rule 19(2), approval Committee may also approve proposal for broad banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity, if it meets the requirement of rules 18.

Accordingly, the proposal is placed before UAC for consideration.

Table Agenda Item No.05:- Request of M/s. Hetero Labs Limited (Unit-IX) a unit in Hetero Infrastructure Ltd –SEZ, NakkapalyMandal, Visakhapatnam for inclusion of Trading Activity in LOA. for export under broad-banding -Reg.

M/s. Hetero Labs Limited (Unit-IX) a unit in Hetero Infrastructure Ltd –SEZ, Nakkapaly Mandal, Visakhapatnam , vide letter dated 12th June,2020 has requested for inclusion of the following Trading Activity in the LoA..

S.No	Name of the Item for trading	Whether bulk Drug/API/ Intermediate	ITC CODE NO.	Annual capacity(volume (Kgs)	Approx value of the goods (Rs.in lakhs)
1	7-IODOPYRROLO(2,1-F)(1,2,4) TRIAZIN-4-AMINE	Intermediate	29339900	10000	10000

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

In terms of Rule 19(2), approval Committee may also approve proposal for broad banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity, if it meets the requirement of rules 18.

Accordingly, the proposal is placed before UAC for consideration.

Table Agenda Item No.06:- M/s.Honour Lab Ltd, a unit in Hetero Infrastructure Ltd –SEZ, NakkapallyMandal, Visakhapatnam for inclusion of additional products in the existing LoA.

M/s.Honour Lab Ltd),a unit in M/s. Hetero Infrastructure Ltd –SEZ, NakkapallyMandal, Visakhapatnam vide letters dated 12.06.2020 has requested for inclusion of additional products in the existing LoA.

Sl. No.	Item of manufacture	APIs/Bulk Drug/ Intermediates	ITC HS code	Projected Annual capacity	Approx value of the goods (Rs. In lakhs)
1	REMDESIVIR	API	29339900	5 Tons	50000
2	DIROXIMEL FUMARATE	API	29171990	5 Tons	5000

The unit has informed that this facility established is for manufacture APIs/Bulk Drug/ Intermediates, a no. of products can be manufactured in this plant. During and after establishment of the facility, action plan was drawn, wherein certain new products are proposed to be manufactured. Now that they have identified the products, they are submitting the same for inclusion in the LoA.

The capacity and project exports due to addition of the above products in LoA for manufacture are already part of their projection given at the time of submission of application. As indicated below, the name of the product may vary from time to time depending on the market conditions.

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. Spl151/P&B/2020dt.13.05.2020 which are valid upto 12.05.2023.

The unit has not furnished NFE projection of the above product.

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.07:- Request of M/s. Mylan Laboratories Limited,Unit-10,Ramky Pharmacy(I) Ltd SEZ, Parwada has requested , for inclusion of additional product under broad-banding in the LOA. for export-Reg.

M/s. Mylan Laboratories Limited,Unit-10,Ramky Pharmacy(I) Ltd SEZ, Parwada vide letter dated 19th June,2020 has requested for inclusion of the following additional products in the LoA..

S.No	Name of the Item for trading	/API/ Intermediate	ITC CODE NO.	Annual capacity((Potential) (Kgs)
1	FAVIPIRAVIR	API/ Intermediate	29242990	20000
2	HYDROXYCHLOROQUINE SULPHATE / HYDROXYCHLOROQUINE SULFATE	API/ Intermediate	29334900	50000

In this regard, the unit has submitted drug licenses vide Nos. L.Dis.No. Sp147/P&B/2020 Dated 4.4.2020 & L.Dis.No Sp146/P&B/2020 Dated 4.4.2020 which are valid upto 03.04.2023.

The unit has not furnished NFE projection of the above product.

In terms of Rule 19(2), approval Committee may also approve proposal for broad banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity, if it meets the requirement of rules 18.

Accordingly, the proposal is placed before UAC for consideration.

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