

AGENDA FOR 118th UNIT APPROVAL COMMITTEEs MEETING FOR THE PRIVATE SEZs OF ANDHRA PRADESH REGION TO BE HELD ON 19.08.2020 AT 11.00 A.M. AT CONFERENCE HALL, ADMINISTRATIVE BUILDING, VISAKHAPATNAM SPECIAL ECONOMIC ZONE, DUVVADA, VISAKHAPATNAM.

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AGENDA FOR 118th UNIT APPROVAL COMMITTEEs MEETING FOR THE SEZs LOCATED IN PRIVATE SEZs OF ANDHRA PRADESH REGION TO BE HELD ON 19.08.2020 AT 11.00 A.M. AT CONFERENCE HALL, ADMINISTRATIVE BUILDING, VISAKHAPATNAM SPECIAL ECONOMIC ZONE, DUVVADA, VISAKHAPATNAM.

PRIVATE SEZs AGENDA

Agenda Item No.1: Ratification of the Minutes of the meeting held on 26.06.2020.

Agenda Item No. 02 : Request of M/s. Eisai Pharmaceuticals India Pvt. Ltd for inclusion of additional product under broad-banding in LOA.

M/s. Eisai Pharmaceuticals India Pvt. Ltd vide letter dated 15.7.2020 has requested for inclusion of the following additional products in the LoA..

S.No	Name of the Product	Category of Business	Annual volume	HSN Code of Product
1	Edoxaban Tosylate	API	1000KG	29420090

The unit has submitted the copy of DRUG LICENSE dated 02.06.2020 in the matter for approval. The drug licence has been observed that it is in the Form-29 for purpose of Examination, Test or Analysis. The unit has also submitted the flow chart of the product.

Further it is also noticed that unit has not enclosed the details of NFE projections in respect of new 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.

Agenda Item No. 03 : : Request of M/s. Eisai Pharmaceuticals India Pvt. Ltd for inclusion of additional product under broad-banding in LOA.

M/s. M/s. Eisai Pharmaceuticals India Pvt. Ltd vide letter dated 15.07.2020 has requested for inclusion of the following additional products in the LoA..

The unit has proposed to undertake the Research & Development activity for the blew mention product.

S.No	Name of the Product	Category of Business	HSN Code of Product
1	Research ^& Development PPAR: Pyrazole derivative	Research &Development	29331990

Unit has informed that these product are new chemicals entities and not approved medicines. Their therapeutic indications are under investigation. These are intermediate developed for tox and clinical studies to establish the therapeutic use..These studies are carried out in Japan, US, EU by related sites of Eisai.

The process development and quality establishment to fulfil the tox and clinical studies are carried out at Eisai Vizag facility. There prepared compounds will be used for internal research purpose only by different sites of Eisai. These products are not for sale.

Hence drug controller authority may not issue drug license for such 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.

Agenda Item No. 04 : Request of M/s. Natco Pharma Limited for inclusion of additional product under broad-banding in LOA.

M/s. **Natco Pharma Limited** vide letter dated 14.7.2020 has requested for inclusion of the following additional products in the LoA..

S .No	Name of the Product	Tablets/ Capsule	ITC HS	UOM	Projected quantity	Approx. Value of the goods in INR
1	Lanthanum Carbonate Chewable Tablets 750mg, 1000mg	Tablets	30049099	Nos	0.24 Million	0.6. Crs

The unit has submitted the copy of DRUG LICENSE vide No.HMF07-14051/88/2020-Tech-DCA in the matter for approval. The drug licence is in the Form-29 for purpose of Examination, Test or Analysis. The unit has also submitted the flow chart of the product. The unit has further informed that the export/import of the products are not in the restricted/prohibited list of goods in terms of ITC(HS).

Further, they have informed that in the present case, the Drug license is obtained for testing purpose only. Hence there will be no commercial sale of the product until the same is commercialized. Hence, they are giving the proposed capacity and approx. Value of the product which will be part of the existing capacity.

The unit vide letter dated. 06.08.2020 has submitted the following revised NFE projection details:-

(Rs. In lakhs)

Export Projected as part of LoA	90000.00
Total Projected Exports due to inclusion of this product	90000.00
Import Projected as part of LoA	19920.00
Projected incremental Imports due to inclusion of this product	0.00
Total Projected Imports due to inclusion of this product	19920.00
Projected NFE after inclusion of this product(*)	70080.00

(*) The project NFE may vary depending on actual. The manufacture of products proposed for testing and analysis will not add to the projected FOB value of exports as the same will be consumed during testing. However, there may be no requirement of imported RM for the same. Hence, the NFE projected may reduce.

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.

Agenda Item No. 05 : Request of M/s. Honour Lab Limited for inclusion of additional product under broad-banding in LOA.

M/s. **Honour Lab Limited**.vide letters dated 31.07.2020 has requested for inclusion of the following additional products in the LoA..

S.No	Item. of. manufacture	API/Bulk/ Drug/ Intermediate	ITC HS	UO M	Projected Annual capacity in kgs	Approx Value of goods (in lakhs)
1	FAVIPIRAVIR	API	29339990	KG	50	75

The unit has submitted DRUG_LICENSE vide No.L.Dis.No.Spl151/P&B/2020 dated 13.05.2020 and is valid upto three years from the date of issue of Drug licences.

The drug licence has been observed that it is in the Form-29 for purpose of Examination, Test or Analysis.

Regarding the details of NFE projections in respect of above product the unit vide letter dated. 07.08.2020 has informed that this product proposed for inclusion in loA are not going to enhance the Exports projected as there are certain products which are approved are stalled for time being for production and this new product will be manufactured in place of them. **Due to this there will be no change in NFE projected and projected exports will remain same.**

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.

Agenda Item No. 06: 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 30th July,2020 has requested for inclusion of the following additional products in the LoA..

S.No	Name of the Product	API / Intermediate/ Bulk Drugs	ITC CODE NO.	UOM	Projecte d annual capacity	Projected annual exports
1	FAVIPIRAVIR	API / Intermediate	29339990	Kgs	250.00	6.72 crs
2	Diroximelfumrate	API / Intermediate	29420090	Kgs	1000.00	1.31.crs

The unit has submitted DRUG LICENSE vide No.L.Dis.No.Spl114/P&B/2020 dated 26.05.2020 which is valid upto three years from the date of issue.

The drug licence is in the Form-29 for purpose of Examination, Test or Analysis.

On verification of the request of the unit it is observed that unit has not enclosed the details of NFE projections in respect of new 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.

Agenda Item No.07:- M/s. Natco Pharma Limited, a unit in Ramky Pharma SEZ, Parawada, Visakhapatnam for inclusion of additional products in the LoA.

M/s. Natco Pharma Limited a unit in Ramky Pharma SEZ, Parawada, vide letters dated. 14.07.2020 has requested for inclusion of following additional products in the existing LoA:-

Sl. No.	Item of manufacture	Tablet / Capsule	ITC HS code	Projected annual Capacity	Projected annual exports in the 5 years INR
1	Lanthanum Carbonate ChewableTablets 250 mg, 500 mg	Tablets	30049099	1.8 Million Nos.	12.5 Crores

The unit has enclosed drug licenses vide F .Nos. HMF07-14051/87/2020-TECH-DCA & HMF07-14051/88/2020-TECH-DCA dt.24.06.2020 and same was revised and valid upto 18.12.2023.

The unit has informed that they propose to manufacture the following Tablets. As the facility established is for manufacture of a no. of Tablets/Capsules, the same shall be utilized for manufacture of additional products also. They shall manufacture the respective products basing on the orders received. This is a continuous process.

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

However, they are giving the proportionate exports to be effected for the below mentioned products as desired which will be part of the existing capacity and projected exports.

Further, they have informed that these products proposed for inclusion in LoA arew not going to enhance the Export projected as there are certain products which are approved are stalled for time being for production and these new products will be manufactured in place of them. Due to this, there will be no change in NFE projected and projected export will remain same. However, the value of goods is mentioned above.

The unit vide letter dated. 06.08.2020 has submitted the following revised NFE projection details:-

(Rs. In lakhs)

Export Projected as part of LoA	90000.00
Total Projected Exports due to inclusion of this product	91250.00
Import Projected as part of LoA	19920.00
Projected incremental Imports due to inclusion of this product	0.00
Total Projected Imports due to inclusion of this product	19920.00
Projected NFE after inclusion of this product(*)	71330.00

(*) The project NFE may vary depending on actuals. The manufacture of products included in the LoA depends on the demand in the market at a given time. Some products may carry higher value and some may carry lower value. The value of the product in line may also reduce suddenly due to competition in international market and fluctuation thereby the projected exports may come down.

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.

Agenda Item No. 08 : Proposal of M/s PharmaZell (India) Pvt Ltd , unit in M/s Ramky Pharma City (India) Ltd SEZ for enhancement of production capacity in LOA.

M/s PharmaZell (India) Pvt Ltd vide letter dated 23.07.2020 has requested for permission to enhance the production capacity of the following approved products in the LoA.

S.N	Name of the Product	Existing capacity	Enhanced capacity	Remark
1	5-AMINO SALICYLIC ACID	450.00 MT	750.00 MT	Approved vide this office letter dated 28.05.2018 (copy enclosed)

The unit has submitted that the production capacity will be increased by way of creation of new additional facility (production building) and additional plant and Machinery in the existing premises and furnished following investment details:-

Estimated Investment (capital expenditure)	FY 2020-21	FY 2021-22	FY 2022-23	Total
	EURO in 000's	EURO in 000's	EURO in 000's	EURO in 000's
5ASA – Expansion – 180 MT	3500	2900	-	6400
5ASA – Expansion – 180 MT	-	-	1500	1500
Other Capex (Regular / General capex)	1267	3250	5850	10367
Total	4767	6150	7350	18267

Estimated Investment (capital expenditure)	FY 2020-21	FY 2021-22	FY 2022-23	Total
	INR in Lakhs	INR in Lakhs	INR in Lakhs	INR in Lakhs
5ASA – Expansion – 180 MT	2800	2320	-	5120
5ASA – Expansion – 180 MT	-	-	1200	1200
Other Capex (Regular / General capex)	1014	2600	4680	8294
Total	3814	4920	5880	14614

The unit has informed that they have already executed LUT on dated. 20.03.2020 for the said calculations. Hence there is not necessity of executing LUT again.

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.

Agenda Item No. 09:- Request of M/s.Divi's Laboratories Limited (SEZ Unit), a unit in M/s.Divi's Laboratories Limited SEZ, Visakhapatnam for inclusion of additional products in the LoA.

M/s.Divi's Laboratories Limited (SEZ Unit) has submitted the letter and requested for approval of manufactured of following drug product under Broad –banding at SEZ unit.

S. No	Name of the product	API/ Nutraceuticals	Annual Production Capacity (In MTs)	ITC code No.
1	FAVIPIRAVIR	API	1,000	29242990

The request of the unit has been observed that the unit has informed that the above product doesn't fall under the prohibited items.

Further it is also observed the application; unit has not enclosed the drug licenses and NFE projections to take further action in the matter.

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.,

The unit has informed that the above product is required for manufacture and expressed urgency for approval of the same in view of the present crisis. Keeping in view of the urgency expressed by the unit, approval granted as a special case due to Corona Pandemic vide this office letter dated. 07.08.2020 for 500 Kgs. subject to the condition to furnish the complete details in respect of the above product viz. The value of the product, NFE details and also advised that the representative to be present in V.C. Copy enclosed.

In response to the unit vide letter dated. 04.08.2020 has submitted NFE details of the above product i.e. Rs. 50 Crores.

Accordingly, the same is placed before UAC for **Ratification**.

Agenda Item No. 10:- Request of M/s. Aurobindo Pharma Limited, unit in APIIC, Multiproduct SEZ for inclusion of additional product under broad-banding in LOA.

M/s. Aurobindo Pharma Limited vide emails dated 24.07.2020 and 07.08.2020 has requested for inclusion of the following additional products in the LoA:-

S.NO	Product Description	Strengt h (mg)	Dosage Form	Vol. of Export in Millions	Proposed Annual Expor t Value (in INR)	Import Cost (in INR)	Net Foreign Exchange Earnings (INR)
1	Bumetanide Tablets USP	0.5	Tablets	4.01	4354250.45	1214230.95	3166809.8
2	Bumetanide Tablets USP	1	Tablets	24.43	35344801.25	14029803.35	21624545.8
3	Bumetanide Tablets USP	2	Tablets	15.59	33835917.5	16789272.05	17417001.8
4	Buspirone Hydrochloride Tablets USP	5	Tablets	63.25	59570504.4	23686865.1	36406332.05

5	Buspirone Hydrochloride Tablets USP	10	Tablets	178.13	221460054.8	122258548.2	101898969.7
6	Buspirone Hydrochloride Tablets USP	10	Tablets	2	13186250	1372722.8	11843814.4
7	Clobazam Oral Suspension	2.5 mg/mL	Suspension	0.18	74566812.1	24388867.65	50716050.55
8	Memantine Hydrochloride Extended-Release Capsules	7	Capsules	1.32	2059541.55	316059.1	1750455.85
9	Memantine Hydrochloride Extended-Release Capsules	14	Capsules	2.15	4659644	719647	3955875
10	Memantine Hydrochloride Extended-Release Capsules	21	Capsules	1.22	3425034.25	595673.55	2842503.4
11	Memantine Hydrochloride Extended-Release Capsules	28	Capsules	10.23	35137212	5651925.7	29609988.1
12	Mesalamine Extended Release Capsules USP	0.375 g	Capsules	46.99	1214352430	71699339.8	1144235035
13	Methocarbamol Tablets USP	750	Tablets	93.09	186603295.5	50227431.05	137483986.8
14	Sevelamer Hydrochloride Tablets 800 mg. - 270Bottle	800mg	Tablets	124.8	870744600	205039219	670229283.4
15	Sitagliptin Tablets	25	Tablets	11.48	59168738.2	6062833.35	53239748.1
16	Sitagliptin Tablets	50	Tablets	44.81	429512179.8	43926898.45	386554466.7
17	Sitagliptin Tablets	100	Tablets	170.44	3236411198	353763825.7	2890452674
18	Varenicline Tablets	0.5	Tablets	3.38	20153111	3415780.6	16812694.8
19	Varenicline Tablets	1	Tablets	54.19	617375553.3	91666385	527731658.3
20	Mirtazapine Tablets 15 mg. - 30Bottle	15MG	Tablets	171.95	362810250	22689838.1	340120411.9
21	Mirtazapine Tablets 15 mg. - 500Bottle	15MG	Tablets	93.27	166523500	7638814.05	158884686
22	Mirtazapine Tablets 15mg 30ct	15mg	Tablets	23.76	50107750	3135241.55	46972508.45
23	Mirtazapine Tablets 15mg 500ct	15mg	Tablets	19.8	35339150	1621594.3	33717555.7
24	Mirtazapine Tablets 30 mg. - 30Bottle	30MG	Tablets	82.36	252573200	16903306.05	235669894
25	Mirtazapine Tablets 30 mg. - 500Bottle	30MG	Tablets	36.36	105490000	5737759.4	99752240.6
26	Mirtazapine Tablets 30mg 30ct	30mg	Tablets	20.68	63444700	4244299.25	59200400.75
27	Mirtazapine Tablets 30mg 500ct	30mg	Tablets	11.88	34434950	1874703.55	32560246.45
28	Mirtazapine Tablets 45 mg. - 30Bottle	45MG	Tablets	40.05	126738700	10964677.3	115774022.7
29	Mirtazapine Tablets 45 mg. - 500Bottle	45MG	Tablets	14.46	40613650	3413083.85	37200566.15
30	Mirtazapine Tablets 45mg 30ct	45mg	Tablets	5.26	16652350	1440064.5	15212285.5
31	Mirtazapine Tablets 45mg 500ct	45mg	Tablets	0.66	1883750	155795.1	1727954.9
32	Losartan Potassium	100	Tablets	89	236324726	92233318.9	144091407.1

	Tablets-100mg						
33	Sulfamethoxazole and Trimethoprim Oral Suspension USP200/40mg Per 5ML.	200/40	OS	0.02	11845020	327077.25	11517942.75
34	Dolutegravir,Lamivudine and Tenofovir 50mg+300mg+300mg Disproxil Fumarate Tablets	50+300+300	Tablets	105	1380160858	498467270	881693588.5

The unit has informed that IT CHS Code of the above products is 30049099.

The unit has submitted DRUG LICENSE for the above products vide License No. L.Dis Nos:3186/MIA/Mfg/2018 dated. 4.10.2018, 5169/MIA/Mfg/2017 dated. 01.2018, 44/MIA/Mfg/2020 dated. 9.01.2020, 198/MIA/Mfg/2020 dated. 05.02.2020, Spl 107/MIA/Mfg/2020 dated. 23.04.2020, 6023/MIA/Mfg/2019 dated. 07.01.2020, 2329/P&B/2017 dated. 18.07.2017, 3890/MIA/Mfg/2017 dated. 29.09.2017 which are valid upto 28.02.2021.

In this regard, it is to submit that the unit has not furnished drug license in respect of Sl. No. 14. It is also observed that name of products and their Strength (mg) at Sl. No. 5 and 6 are same.

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 same is placed before UAC for consideration.

Agenda Item No.11:- 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 above proposal has been placed in the UAC meeting held on 26.06.2020 and UAC has deferred the same as the unit has not furnished the complete details relating to the proposal i.e. NFE projections. The unit has been advised to submit the details relating to the projected exports and NFE for taking further action into the matter.

In response the unit vide letter dated. 23.07.2020 has informed that they have the facility established is for manufacture of APS/Bulk Drugs and Intermediates and many of products manufactured on campaign basis on customer orders demand.

Certain new products are to be undertaken and capacity projected exports due to addison of new products in LoA are already part of their projections given at the time of LoA renewal. and these additional products manufactured within the same capacity and facility. Only products may vary, and this will be within the Limits of LoA values declared. So there is no change in projection values either in products or material and NFE will be positive as per LoA approved by office.

In view of the above, the request of the unit has been considered and approved vide this office letter dated. .08.2020 (copy enclosed) as detailed below:-

S.No	Name of the Item for trading	/API/ Intermediate	ITC CODE	Annual capacity
1	FAVIPIRAVIR	API/ Intermediate	29242990	135 Kg.
2	HYDROXYCHLOROQUINE SULPHATE / HYDROXYCHLOROQUINE SULFATE	API/ Intermediate	29334900	50 MT

Accordingly, the same is placed before UAC for **Ratification**.
