# AGENDA FOR THE UNIT APPROVAL COMMITTEES MEETING FOR THE PRIVATE SEZS OF ANDHRA PRADESH, TELANGANA TO BE HELD ON 10.01.2023 UNDER THE CHAIRMANSHIP OF SHRI D.V.SWAMY, IAS, ZONAL DEVELOPMENT COMMISSIONER THROUGH WEBEX

### VSEZ AGENDA – ANDHRA PRADESH

### Agenda Item No.1:- Ratification of the Minutes of the meeting held on 09.12.2022

The minutes of the UAC meeting held on 09.12.2022 has been circulated to all the members of the UAC and also placed on the VSEZ website. No comments have been received from the members of UAC. The minutes are placed before UAC for ratification.

<u>Agenda Item No.02</u>:- Permission to install Airtel Mini Tower at M/s. Gland Pharma Ltd. Premises-Reg.

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M/s. Gland Pharma Ltd vide letter dated 16.11.2022. has informed their business is impacting due to poor network and requested for permission to install Airtel Mini Tower on their unit's building to resolve the problem. The equipment is said to be installed free of cost by the service provider.

The unit intimated that the following technical requirements for the installation required.

- Permission to install 2 nos. 9mts poles on terrace.
- Required 2x2.5 mtr space for BTS & Battery Bank installation on terrace.
- Required 3KW 3 Phase AC power to operate BTS and Battery Bank for 24/7 for uninterrupted network coverage.

Further the unit vide letter dated 14.12.2022 has informed that they have been facing the network issue and as their maximum employees are using airtel network and connected with CUG Airtel which is impacting their Productivity and business. Upon complaint, Airtel office has visited their site for survey and suggested to install micro tower at their site for free of cost.

M/s Gland Pharma confirmed that they will only provide installation area and power supply from their end and there is no rentals agreement between the unit and M/s. Airtel.

The unit assured that this Micro tower exclusively used for their unit only and this Service will not be extended to any other site located at VSEZ.

In view of the above the unit has to accord permission and instruct the concerned department to allow the material required for installation of the above micro tower when it reached VSEZ main gate.

Submitted before UAC for consideration please.

Agenda Item No.3: Request of M/s. Kusalava International Ltd. a unit in VSEZ for permission to allow solar modules for setting up a 0.9 MV Solar Power Plant at their unit situated at Plot N1, Phase-III, VSEZ, Duvvada - Reg.

M/s. Kusalava International Limited a unit in VSEZ has informed that they are planning to install Solar Power Generating system of 0.9 MV capacity in the premises of their unit for captive consumption and requested for permission to allow solar modules into their factory.

The unit has informed that due to power cuts in summer the unit decided to install the solar power generation equipment of capacity 0.9 MV in the premises of the unit for their captive consumption.

Further the unit has informed that they approached M/s. Enerparc Energy Pvt. Ltd. Bengaluru and they agreed to supply the material such as PVmodules, Inverters, S-roof top, DC cables, C Cables, SCADA, LT Panels for install 0.9 MV Solar plant in the premises of the unit, for which the cost of Rs. 3.84 Crores approximately. As such, the unit has also furnished a Techno Commercial proposal of M/s. Enerparc Energy Pvt. Ltd. Benagaluru.

In the regard, kind reference is invited to DoC's Power Guidelines O.M. No. K-43014(16)8/2020-SEZ dated 7<sup>th</sup> June, 2021, allowing setting up of "non-conventional power plant with permission of Unit Approval Committee within the premises of an SEZ unit for the exclusive purpose of captive consumption subject to the condition that no tax/ duty benefits stipulated under Section 26 of the SEZ Act, 2005 shall be available for setting up as well as operations and maintenance of such power plant. Such Captive generative Power Plants shall comply with all rules, regulations and technical standards framed under the Electricity act, 2003 as amended from time to time. Captive generative power plants with capacity 500 KWPH and above has to be re-registered with Central Electricity Authority.

As per which, a unit may set up a non-conventional power plant with the approval of the Unit Approval Committee within the premises of the unit for the exclusive purpose of captive consumption subject to the condition that no tax/ duty benefits stipulated under Section 26 of the SEZ Act, 2005 shall be available for setting up as well as operations and maintenance of such power plant. Further, it is indicated that Captive Generative Power Plants with capacity 500 KWPH and above has to be reregistered with Central Electricity Authority.

In the instant case, the unit has not submitted the copy of re-registration with Central Electricity Authority. Whereas, the request of the unit is of capacity of 0.9 MV(900 KW) which is above 500 KW and hence the re-registration with Central Electricity Authority is required.

In view of the above, the same has been informed vide this office letter dated 02.11.2022 that the unit shall submit a detailed proposal for installation of power plant along with the copy of NOC issued by the Developer i.e., VSEZ Authority, Details of the material, Value of the material, Cost of the project, name of the executing agency, copy of agreement reached between the agency and the unit and a copy of the re-registration certificate obtained from Central Electricity Authority..

In response the unit vide letters dated 07.12.2022 and 20.12.2022 has furnished the following documents as detailed:

1. Techno Commercial Proposal of M/s. Energarc Energy Pvt. Ltd,

- Two Purchase Order copies duly indicating the Details of material, value of material and
   Name of the executing agency.
  - 3. Copy of the agreement between M/s. Kusalava International Limited and M/s. Enerparc Energy Pvt. Ltd. duly indicating the Cost of the Project of Rs. 3.80 crores.
    - 4. Copy of the application submitted to Central Electricity Authority

In view of the above documents, it is observed that the unit did not submit the copy of approval with Central Electricity Authority and NOC from VSEZ Authority.

Further, the unit vide above letter has informed that based on order M/s. Enerparc Energy Pvt. Ltd. had sent Solar related items through transport in early October, 2022, since the items are being in transport from the last two months, it is getting damaged due to improper handling by them and charging huge demurrages. Due to delay in project they are not able to utilize solar power and they are losing so much money.

In the event above, the unit has informed that the installation process will take place nearly two months time in meantime they will get the necessary approvals and after the approval only they will put their solar plant into operation.

Hence, the unit has requested to allow solar project related items into their factory for installation .

Accordingly, the proposal is placed before UAC for consideration.

# Agenda Item No.4: Proposal of M/s.Arrow Technology for setting up a new Unit in VSEZ, Duvvada, Visakhapatnam for manufacture of Laser Diode - Reg.

M/s.Arrow Technologies has submitted a proposal for setting up of a Unit in VSEZ, Duvvada, Visakhapatnam for manufacture of Laser Diode. The details of the proposal is furnished hereunder:

1	Proposal	Proposal of M/s.Arrow Technology for setting up of a unit for			
		manufacture in VSEZ, Duvvada, Visakhapatnam			
2.	Application Fees	DD for an amount of Rs.10,000/- submitted			
3.	Name & address of the	M/s.Arrow Technology			
	Compay (Regd.office)	Flat No.303, Second Floor, Mahalaxmi Mansion, Phase-II,			
		Mathrusri Nagar, Kurmannapalemn, Vadlapudi Post,			
		Visakhapatnam-530049			
4.	Telephone/E-mail	+91 8866411387			
		ashishsingh13011998@gmail.com			
5.	Constitution of the	Partnership Firm			
	Company				
6.	Items of Manufacture	Laser Welding/cutting machine			

		2. Laser Soldering/Soldering 87 Nos.
		machine
		3. Laser Diod, Cooling Systems, 506 Nos.
		Laser Optical Path, Laser Power
		Driver, Laser Crystal Rod, Lamp,
		Eye Protector, Micro Scope,
		Focus Lens, Expander
		Input,Ouput, Front Mirror, Back
		Mirror, Power Driver,Fan Power
		MCB, LED Light, Other Laser
		Manufacturing material as
		required
7.	Import Requirements	Capital Goods Rs.30.00 lakhs
		Raw material, components, Rs.315.00 lakhs
		consumables, packing material, fuel etc
	La dinana ana Dannina ao ao ta	for 5 years
8.	Indigenous Requirements	Capital Goods Rs.20.00 lakhs
		Raw material, components, Rs.190.00 lakhs
		consumables, packing material, fuel etc
9.	FoB value of Exports	for 5 years Rs.635.00 lakhs
9.	over a period of five	173.000.00 lakiis
	Years	
10.	NFE over a period of five	Rs. 290.00 Lakhs
	years	- 1. 0 0. 0. 0. 0. 0. 0. 0. 0. 0. 0. 0. 0. 0.
11.	Investment	Rs.50.00 lakhs
12.	Details of source of	Self Investment
	Finance	
13.	Foreign Technology, if	Nil
	any	
14.	Requirement of Space	Built-up Space – 100 Sq.Mts.
15.	Requirement of Water	9 KL
16.	Requirement of Power	25 KVA
17.	Employment	28 ( 22 Men, 6 women)
18	Whether the applicant	NO
	has been issue any	
	LoA/LOP under	
	SEZ/EOU Scheme, if so	
	details	

As per the project report there are two partners, the details of the partners are furnished hereunder:

- 1. Mr. Ashish Phoolanbhai Singh has completed his Higher Secondary and then went on to complete DNS in Merchant Navy. He has worked as an Accountant for 2 years with Shivaay Jewels.
- 2. Avinash Jadhav has completed his graduation in B.Pharmacy and has about 11 years experience working as Area Manager in this field with Cydus Cadila Pharma.

### M/s.Arrow Technology has furnished the following:

- 1. Prescribed application Form-F
- 2. Detailed Project Report
- 3. Copies of Aadhar Cards of the Director
- 4. Copy of the PAN card of the Firm
- 5. Copy of the PAN Card of the Director
- 6. Memorandum of Association
- 7. Article of Association
- 8. Incorporation Certificate
- 9. IT Returns of one of the partner for the last two years submitted.

Proposal placed before Unit Approval Committee for consideration

#### **PVT SEZs Agenda – Andhra Pradesh**

### Agenda Item No.1:- Ratification of the Minutes of the meeting held on 09.12.2022

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# Agenda Item No.02:- Request of M/s. Deccan Fine Chemicals (India)Private Limited (SEZ Unit) for inclusion of additional product in the existing LoA - Reg.

M/s. Deccan Fine Chemicals (India)Private Limited (SEZ Unit) has requested for inclusion of the following additional products in the existing LoA. As their customers have requested them to send the following products samples of 20 Kg each. The unit intend to send these samples to their customer for the purpose of evaluation and registering them

SI.No.	Item of manufacture	ITC HS Code	Projected Annual Capacity (In Kgs.)
1.	Rinskor	38089327	20
2.	Xemium	38089250	20
3.	Plinazolin	38089199	20
4.	Quinoxyfen	38089290	20

5.	KNF-1934	38089250	20
6.	Arylex	38089390	20
7.	XDE-747	38089290	20
8.	Ethiprole	38089199	20
9.	Pavecto	38089250	20
10.	Oxaziclomefone	38089390	20

The unit has informed that there will not be any change in the projections viz imports, exports and NFE and any additional impact upon addition of the above products as the same will be manufactured within the overall capacity permitted earlier.

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

The unit has informed that they had CFO for manufacture of the above products.

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 the UAC for consideration.

### Agenda Item No.03:- Request of M/s. Deccan Fine Chemicals (India)Private Limited (SEZ Unit) for inclusion of additional product in the existing LoA - Reg.

M/s. Deccan Fine Chemicals (India)Private Limited (SEZ Unit) has requested for enhancement of the annual capacity of the following product, as their customer, M/s. Syngenta has requested them to enhance the quantity and in order to meet the demand, the unit has requested for enhancement of the production capacity.

SI.No	Name of the approved product	ITC HS Code	Approved Capacity (In MT)	Proposed enhancement in capacity (In MT)
1.	NBE-dichloromethylene 2,3,4,6,7,8-hexahydro-1H- 1,4-methanonaphthalen5-one oxime.(DCO-NBE or STL8) or DICHLOROOXIME-NBE TECH	29280090	20	120

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

The unit has informed that they had CFO for manufacture of the above products.

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 the UAC for consideration.

# Agenda Item No.04:- Request of M/s. Divi's Laboratories Limited (DCV SEZ Unit) for inclusion of additional product in the existing LoA - Reg.

M/s. Divi's Laboratories Limited (DCV SEZ Unit) has requested for inclusion of the following additional product in the existing LoA. The details of the products proposed for inclusion is furnished hereunder:-

SI.No.	Name of the	Annual of	API/Intermediate	ITCHS	Restricted/	NFE
	Product	Production		code	Free	details for
		Capacity				5 years
1.	Tert-butyl 4- (6- aminopyridin- 3- yl)piperazine- 1-carbozylate	5 MT	Intermediate	29333990	Free	Rs.150 cr.

The unit has submitted the process details, critical equipment, raw-materials and the same are enclosed to the agenda.

Since the product proposed is an Intermediate as such the Unit has submitted an Undertaking that the Drug License for the Intermediate product is not required.

The unit has declared that the above products are not in the restricted / prohibited 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 terms of manufacture or service activity.

Accordingly, the proposal is placed before the UAC for consideration.

### <u>Agenda Item No.05</u>:- Request of M/s. Divi's Laboratories Limited (SEZ Unit) for inclusion of additional product in the existing LoA - Reg.

M/s. Divi's Laboratories Limited (SEZ Unit) has requested for inclusion of the following additional product in the existing LoA. The details of the products proposed for inclusion is furnished hereunder:-

SI.N	Name of the	Annual of	API /	ITCHS	Restricted/	NFE details
0.	Product	Production	Intermediate	code	Free	for 5 years
		Capacity (In				
		MTs)				

1.	Tert-butyl(5S,6R)-6- methyl-2-oxo-5- phenylpiperidin-3- yl)Carbamate/Lacta m C1 1010409-F	4.00	Intermediate	2933799	Free	Rs.200.00 Cr.
2.	(R) -5,8-dichloro-7- (methoxy(oxetan-3- yl)methyl)isochrom an-I-one(PF- 0784500)	0.1	Intermediate	2932999	Free	Rs.100.00 Cr.
3.	2 (n-butyl)-4-chloro- 5-formyl imidazole	180.00	Intermediate	2933299 0	Free	Rs.144.00 Cr.
4	Rizatriptan Benzoate [Chemical Name: N, N-Dimethyl-2-[5- (1,2,4-triazol-1- ylmethyl)-1H-indol- 3-yl] ethylamine benzoate]	0.500	API	2933999 0	Free	Rs. 150.00 Cr.

The unit has submitted the process details, critical equipment, raw-materials and the same are enclosed to the agenda.

Since the product proposed in respect of SI. No. 1 to 3 are an Intermediate as such the Unit has submitted an Undertaking that the Drug License for the Intermediate product is not required.

The unit has submitted Drug License for the above product in respect of SI. No. 4 vide License No. File No. HMF07-14051/2313/2022-ADMIN-DCA dated: 15.12.2022 which is valid upto **17.01.2023.** 

The unit has declared that the above products are not in the restricted / prohibited 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 terms of manufacture or service activity.

Accordingly, the proposal is placed before the UAC for consideration

# Agenda Item No.06:- Request of M/s. Divi's Laboratories Limited (DSN SEZ Unit) for inclusion of additional product in the existing LoA - Reg.

M/s. Divi's Laboratories Limited (DSN SEZ Unit) has requested for inclusion of the following additional product in the existing LoA. The details of the products proposed for inclusion is furnished hereunder:-

SI.N	Name of the	Annual of	API /	ITCHS	Restricted/Fr	NFE
0.	Product	Production	Intermediate	code	ee	details
		Capacity (In				for 5
		MTs)				years
1.	Sodium	5 MT	API	2931390	Free	Rs. 50 cr.
	Alendronate /			0		
	Alendronate					
	Sodium / Sodium					
	Alendronate					
	Trihydrate (Varaahi)					

The unit has submitted the process details, critical equipment, raw-materials and the same are enclosed to the agenda.

Since the product proposed is an Intermediate as such the Unit has submitted an Undertaking that the Drug License for the Intermediate product is not required.

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

The unit has submitted Drug License for the above product vide License No. File No. HMF07-14051/2314/2022-ADMIN-DCA dated: 15.12.2022 which is valid upto **17.01.2023**.

### The name of the product in Drug License is Alendronate Sodium In House.

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 the UAC for consideration

## Agenda Item No.07:- Request of M/s. Aragen Life Sciences Pvt. Ltd. a unit in Ramky Pharma SEZ, Parawada for inclusion of additional product in the LoA - Reg.

M/s. Aragen Life Sciences Pvt. Ltd. a unit in Ramky Pharma SEZ, Parawada, vide letter(s) dated. 12.12.2022 and 15.12.2022 has requested for inclusion of following additional product in the existing LoA:-

S. No	Name of the Product	Intermediate /API/Bulk Drug	HSN Code	Annual Capacity in Kg.	Projecte NFE USD	d in
1	ethyl 2-(benzyloxy)-4-hydroxy-6- methylnicotinate[CDS-045/STG- 01]	Intermediate	2931909 0	1500 kg		
2	ethyl 2-(benzyloxy)-4-methoxy-6-methylnicotinate[CDS-045/STG-	Intermediate	2931909 0	800 kg		

	02]				
3	(2-(benzyloxy)-4-methoxy-6-methylpyridin-3-yl)methanol [CDS-045/STG-03]	Intermediate	2933199 0	600 kg	612747
4	2-(benzyloxy)-3-(chloromethyl)-4- methoxy-6-methylpyridine [CDS-045/STG-04]	Intermediate	2933399 0	600 kg	
5	2-((2-(benzyloxy)-4-methoxy-6-methylpyridin-3-yl)methyl)isoindoline-1,3-dione [CDS-0373/STG-01]	Intermediate	2933599 0	600 kg	
6	(2-(benzyloxy)-4-methoxy-6-methylpyridin-3-yl)methanamine [CDS-0373/STG-02]	Intermediate	2933399 0	500 kg	
7	(E)-3-(4-bromophenyl)acrylic acid [CDS-0372/STG-01]	Intermediate	2921449 0	500 kg	
8	methyl (E)-3-(4- bromophenyl)acrylate [CDS- 0372/STG-02]	Intermediate	2921449 0	500 kg	450000
9	methyl (E)-3-(4- (phenylethynyl)phenyl)acrylate [CDS-0372/STG-03]	Intermediate	2921449 0	500 Kg	
10	(E)-3-(4- (phenylethynyl)phenyl)allyl (2,2,2- trifluoroacetyl)glycinate [CDS-0372/STG-04]	Intermediate	2921449	500 Kg	
11	(R)-1-Phenylethan-1-aminium (2s,3s)-3-(4-phenyl ethylnyl)phenyl)-2-(2,2,2-Trifluoroacetamido)pent-4-enoate [CDS-0372/STG-05]	Intermediate	2921449	200 Kg	

The unit has informed that they have taken order to manufacture the above product. In this regard they have submitted process flow chart, Route of Synthesis and List of Raw materials.

The unit vide letter(s) / Undertaking dated. 12.12.2022 and 15.12.2022 has informed that the above product is intermediate. Hence drug license is not required.

The unit has also informed that the above products are free for export and submitted copy of ITCHS Export Policy, 2019 in respect of above ITCHS codes as a proof.

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.

## Agenda Item No.08:- Request of M/s. Aragen Life Sciences Pvt. Ltd. a unit in Ramky Pharma SEZ, Parawada for inclusion of additional product in the LoA - Reg.

M/s. Aragen Life Sciences Pvt. Ltd. a unit in Ramky Pharma SEZ, Parawada, vide letter dated. 12.12.2022 has requested for inclusion of following R&D services in the existing LoA:-

Proposed Services	SAC CODE	Annual Capacity
R& D Services in Area of Chemistry, Discovery, Integrated Chemistry & Analytical Services and scale up projects	998141	Milligram $\rightarrow$ Gram $\rightarrow$ Kg $\rightarrow$ 15 Kg scale up research projects for the products were manufactured by the unit.

### **Commercial Opportunity:**

Most of our proposed R & D Services will be executed from our existing clients and rarely from new clients.

### **Investment Details:**

Particulars	Value in Lakhs
Land	Nil
Building	646
Plant & Machinery	2103
Indigenous (5 years)	1950
Imported (5 years)	2340
Total	7039

### Revenue Projections (Value in Lakhs) for Five years

		FY-23-24	FY-24- 25	FY-25- 26	FY-26- 27	FY-27- 28	
S.No	Particulars	1 <sup>st</sup> Year value in lac	2 <sup>nd</sup> Year value in lac	3 <sup>rd</sup> Year value in lac	4 <sup>th</sup> Year value in lac	5 <sup>th</sup> Year value in lac	Total value in lac
1	FOB value of Exports	700	1000	2000	3000	5000	11700
2	CIF value of Imports	140	200	400	600	1000	2340
3	Others (Forex Outflow):						
	Lump sum Know How fee	0	0	0	0	0	0
	Commission of Export etc						
	Foreign Travel						
	Total (2+3)	140	200	400	600	1000	2340
	Net Foreign Exchange Earnings	560	800	1600	2400	4000	9360
4	Indigenous CG/RM's	100	150	200	500	1000	1950

### **R&D** team & Management:

The unit has informed that they are are hiring highly skilled and dedicated team as per below for our proposed activity.

	S.No	No of employees FY 24	Manager Category	Tech Skilled	Un Skilled	Total
•	1	Men	2	6	4	12

2	Women	2	6	2	10
				Grand total	22

Details of Exports & Imports of existing manufacturing Unit for the last four years.(in Lakhs)

Particulars	1 <sup>st</sup> Year	2 <sup>nd</sup> Year	3 <sup>rd</sup> Year	4 <sup>th</sup> Year
FOB Value of Exports in first four years	4402.73	6833.92	9098.29	7171.08
Foreign Exchange out go	2065.92	3858.80	1360.95	2513.97
Net foreign Exchange earnings for the first year (1)-(2)	2336.81	2975.12	7737.34	4657.0

The above request has been forwarded to the Specified Officer, Ramky SEZ for necessary comments.

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.

<u>Agenda Item No.09</u>:- Request of M/s. Pfizer HealthCare India Ltd. Unit in M/s Ramky Pharma City (India) Ltd SEZ, Parawada, Visakhapatnam District for inclusion of additional product under broad-banding in LOA – Reg.

M/s. Pfizer HealthCare India Ltd. vide letter dated 29.12.2022 has requested for inclusion of the following New products in the existing LoA:-

SI.NO.	Item of Manufacture	Product	ITCHS	UOM	Projected Annual Capacity(NOS )
1	50% Dextrose Injection, USP, 25 grams / 50 mL, (0.5 g/mL)	Injectables	30049099	VIAL	1,05,660

The unit has submitted that this facility established is for manufacture of Injectables, a no.of products can be manufacture 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 projected exports due to addition of the below products in LOA does not change as presently the product is being proposed to manufacture for testing and Analysis.

The unit has submitted Drug License for the above product vide License Nos. File No. HMF07-14051/2165/2022-ADMIN-DCA dated: 29.11.2022 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.

<u>Agenda Item No.10</u>:- Request of M/s. Ajinomoto Bio Pharma Services India Pvt. Ltd. Unit in M/s Ramky Pharma City (India) Ltd SEZ, Parawada, Visakhapatnam District for inclusion of additional product under broad-banding in LOA – Reg.

M/s. Ajinomoto Bio-Pharma Services India Pvt. Ltd. Unit vide letter dated 29.12.2022 has requested for inclusion of the following additional products in the LoA.

SI.	Name of the Product	Category of	Porbable ITC	Capacity
No.		Business	HS Code	(Kg's/Per
				Day)
1	(R)-7-(Benzyloxy)-N-(2,4-	Intermediate	29420090	67.00
	difluorobenzyl)-4-methyl-6,8-dioxo-			
	3,4,6,8,12,12a-hexahydro-2H-			
	pyrido[1',2':4,5]pyrazino[2,1-			
	b][1,3]oxazine-9-carboxamide (DOL-2)			

The unit has informed that they are expecting to start-up of their Manufacturing Block II during 1<sup>st</sup> week of February,2023. On completion of first trail product manufacturing, they will again declare commercialization of the block. Similarly, they also request to add the above product in LoA as they intend to manufacture the same which is an intermediate product do not require drug license. All the existing products they are manufactured in Manufacturing Block-I so far covered by LoA has also been intended to produce from the new block also.

They have also informed that the above products are Intermediates and not required Drug license.

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.11:- M/s. Honour Lab, a unit in M/s. Hetero Infrastructure Ltd. SEZ, N. Narasapuram (V), Nakkapally Mandal, Visakhapatnam for inclusion of additional products in the LoA - Reg.

M/s. Honour Lab Limited vide letter dated 19.12.2022 has requested for inclusion of the following additional products in the LoA.

S. No	Item of manufacture	API/Bulk/	ITC HS	Projected	Approx	
		Drug/		Annual	Value	of
		Intermediate		capacity in kgs	goods	(in
					lakhs)	
1	UBROGEPANT	API	2933599	50 KGS	1000	
			0			
2	TAFAMIDIS HYDRATE	API	2918990	2 KGS	10	
			0			

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.

These product proposed for inclusion in LoA are not going to enhance the Export 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. <u>Due to this there will be no change in NFE projected and projected exports will remain same.</u>

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).

The unit has submitted Drug License for the above product vide License Nos. File No. HMF07-14051/2025/2022-ADMIN-DCA dated: 16.12.2022 which is valid upto **29.08.2023 for export**.

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.

<u>Agenda Item No.12</u>:- M/s. Hetero Drugs Limited (Unit-IX) , a unit in M/s. Hetero Infrastructure Ltd. SEZ, N. Narasapuram (V), Nakkapally Mandal, Visakhapatnam for inclusion of additional products in the LoA - Reg.

M/s. Hetero Drugs Limited (Unit-IX) vide letter dated 03.01.2023 has requested for inclusion of the following additional products in the LoA.

S.No	Item. of. manufacture	API/Bulk/ Drug/ Intermediate	ITC HS	Projected Annual capacity in kgs	Approx Value of goods (in lakhs)
1	2- ACETOXYETHYL ACETOXYMETHY L ETHER	INTERMEDIAT E	2933999 0	50 KGS	1250

The unit has informed that as part of the items being manufactured in this facility, they have taken approval for no. of items for manufacture. The production of a specific product depends on the approved product profile and the order base. The unit has been granted LOA vide above referred letter for manufacture of various products with addition to the product list from time to time.

As the facility established is for manufacture of APIs/Intermediates, a number of products can be manufactured using the same facility depending on the demand for the product and order base.

The unit has informed that in view of adding of these new products, there will be no change in Annual capacity or capacity enhancement and NFE:

Further they have informed that, the drug licenses already obtained for the main product stands same and there is no separate drug license required for Intermediate. These intermediate shall become final product after the balance stages in the receiving unit. We are therefore enclosing herewith copies of Drug licenses of the main products of these Intermediates.

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 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.13:- Request of M/s. APL Health Care Ltd., unit in APIIC, Multiproduct SEZ for inclusion of the final products for making authorized operations in LOA - Reg.

M/s. APL Health Care Ltd. vide email dated 12.12.2022 and 19.12.2022 has requested for inclusion of the following New products in the existing LoA:-

S.No.	Name of the Product	Strength	Dosage Form	ITCHS Code	Annual Capacity in Mil- lions
1	Rufinamide Tablets USP	200 mg	Tablets	30049099	0.19
2	Rufinamide Tablets USP	400 mg	Tablets	30049099	0.52
3	Fosfomycin Tromethamine Granules for Oral Solution	3 gm	Sachet pack	30049099	0.03
4	Ibuprofen Oral Suspension USP	100 mg / 5 mL	Oral Solution	30049063	1.42
5	Levetiracetam Oral Solution USP	100 mg/ml	Oral Solution	30049082	0.95

The unit has submitted Drug License for the above products vide File Nos. HMF07-19024/271/2022-DD-DDCA dated: 01.12.2022 which is valid upto 31.03.2026 and File No. HMF07-19024/152/2022-DD-DDCA dated: 30.08.2022 which is valid upto 31.03.2026.

The unit has projected USD 7952158 towards NFE consequent upon inclusion of the above products.

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.14:- Request of M/s. International Trimmings & Labels (Vizag) India Private Limited a unit in M/s Brandix India Apparel City (P) Ltd SEZ for cancellation of Leased Land Agreement of Plot # 7A, BIAC SEZ – Reg.

M/s International Trimmings & Labels (Vizag) India Private Limited a unit in M/s. Brandix India Apparel City Pvt Ltd (BIACPL) SEZ, Achuthapuram Mandal, Visakhapatnam vide letter dated: 23.07.2022 received on 14.09.2022 has informed that they leased a land of 1.1 Acres in BIAC SEZ in Plot # 7A from the year of 2014.

Further they informed that they had an unexpected delay in their plant expansion and construction of the proposed factory building due to circumstances prevailed during the said period. In order to address the issue instantly as an alternate option, a built-up space in BIAC-SEZ in Staging Unit-3 (Plot-8B) measuring around 5,580 Sqft which become available to them was secured in order to continue their operation uninterrupted. Hence they have requested for approval for the cancellation of the land sub-lease agreement to facilitate the handing over of the leased land which is not required for their operation in the foreseeable future, back to BIAC SEZ. They have submitted copy of "No Ohjection Certificate" from the Developer, BIAC and copy of Sub-Lease Agreement dated: 17.03.2016.

In this this regard it is to submit that M/s International Trimmings & Labels (Vizag) India Private Limited was granted approval vide this office letter dated: 02.03.2022 for additional space in the Staging Unit III to expand the operations in M/s.Brandix India Apparel City Private Limited SEZ subject to the condition to they shall submit a revised Lease deed which has been approved by the UAC in its meeting held on 25.02.2022.

The request of the unit has been forwarded vide this letter dated: 29.11.2022 to the SO, Brandix SEZ and advised to inspect the land proposed for cancellation and to see whether any infrastructure or duty exempted material is available and furnish a report for taking further action in the matter.

In response the SO, Brandix SEZ vide letter dated: 12.12.2022 has informed that the leased land of M/s International Trimmings & Labels (Vizag) India Private Limited at Plot No.7A, BIAC SEZ which was taken from M/s. Brandix India Apparel City Pvt. Ltd. was inspected and found that there is no infrastructure or duty exempted material available in the plot area. Hence the leased land agreement proposed for cancellation of the Unit may be considered.

The request of the Unit for the cancellation of the land sub-lease agreement to facilitate the handing over of the leased land back to BIAC SEZ is placed before UAC for consideration.

Agenda Item No.15:- Request of M/s. Indip Industrial Parks (Vizag) Pvt. Ltd. Co-Developer in M/s Brandix India Apparel City (P) Ltd SEZ for change in Directors of their SEZ – Reg.

Proposal of M/s. Indip Industrial Parks (Vizag) Pvt. Ltd. Co-Developer in M/s Brandix India Apparel City (P) Ltd SEZ, Atchuthapuram, Visakhapatnam, Andhra Pradesh for change in Directors.

The Co-Developer vide letter dated 07.12.2022 has stated that there is a change in Board of Directors of their Company. The list of Directors before and after is as under:

#### **New Directors:**

S.No.	Name of the Director	DIN Number
1	Shalini Anand	09517734
2	Yogesh Gulati	00144758

#### **Exit Directors:**

S.No.	Name of the Director	DIN Number
1	Jasmeet Singh Chhabra	00930654
2	Amrendra Kumar Singh	07238010
3	Kirti Sharma	07370828

In this regard, the Co Developer has submitted the following details in respect of new Directors:

- 1) ROC filings (Form No. DRI-12 and GAR7 Challan)
- 2) Copy of Board Resolutions for the Appointment of new Directors
- 3) Copy of PAN and Aadhar Card of new Directors

The proposal of the Co-Developer is placed before UAC for approval, in terms of Instruction No. 109 dated 18.10.2021 of DOC, New Delhi.

Agenda Item No.16:- Request of M/s Brandix Apparel India Pvt. Ltd., Unit – I a unit in M/s Brandix India Apparel City (P) Ltd SEZ for permission to procure HSD at duty free rate from HPCL - Reg.

M/s Brandix Apparel India Pvt. Ltd., Unit – I a unit in M/s Brandix India Apparel City (P) Ltd SEZ vide their letter dated 17.10.2022 has requested for renewal of approval for procurement of High Speed Diesel Oil at duty free rate from HPCL, Visakhapatnam refinery for plant DG set in case of power failures and avoid downtime for production and informed that their monthly consumption is 10 KL. The unit has submitted copies of Explosive License issued by Joint Chief Controller of Explosives, Chennai.

It is to submit that the unit has been granted permission vide this office letter dated. 30.05.2022 for procurement of 60 KL of HSD for a period of six months i.e from 17.05.2022 to 16.11.2022.

The Specified Officer, Brandix SEZ vide letter dated: 14.12.2022 has submitted consumption details for the period from 15.04.2022 to 25.10.2022 wherein it is informed that the unit has procured 12 KL quantity of HSD without payment of duty during the above period. During the said period they have utilized 2.76 KL of HSDO out of 12.5 KL (Opening Balance 0.5KL + procured 12.0 KL) and as on 25.10.2022 the closing balance of HSD is 9.74 KL.

The request of the unit for procurement of 60 KL per month of HSD for further period of six months is placed before the Approval Committee for considerations.

Agenda Item No.17:- Request of M/s Brandix Apparel India Pvt. Ltd., Unit – II a unit in M/s Brandix India Apparel City (P) Ltd SEZ for permission to procure HSD at duty free rate from HPCL - Reg.

M/s Brandix Apparel India Pvt. Ltd., Unit – II a unit in M/s Brandix India Apparel City (P) Ltd SEZ vide their letter dated 17.10.2022 has requested for renew of approval for procurement of High Speed Diesel Oil at duty free rate from HPCL, Visakhapatnam refinery for plant DG set in case of power failures and avoid downtime for production and informed that their monthly consumption is 15 KL. The unit has submitted copies of Explosive License issued by Chief Controller of Explosives, Nagpur.

It is to submit that the unit has been granted permission vide this office letter dated. 30.05.2022 for procurement of 60 KL of HSD for a period of six months i.e from 17.05.2022 to 16.11.2022.

The Specified Officer, Brandix SEZ vide letter dated: 14.12.2022 has submitted consumption details for the period from 17.05.2022 to 16.11.2022 wherein it is informed that the unit has procured 20 KL of HSD without payment of duty during the above period. During the said period they have utilized 7.15 KL of HSDO out of 23.22 KL (Opening Balance 3.2 KL + Procured 20 KL)) and as on 16.11.2022 the closing balance of HSD is 15.35 KL.

The request of the unit for procurement of 60 KL per month of HSD for further period of six months is placed before the Approval Committee for considerations.

<u>Agenda Item No.18:-</u> Request of M/s Brandix Apparel India Pvt. Ltd., Unit – III a unit in M/s Brandix India Apparel City (P) Ltd SEZ for permission to procure HSD at duty free rate from HPCL - Reg.

M/s Brandix Apparel India Pvt. Ltd., Unit – III a unit in M/s Brandix India Apparel City (P) Ltd SEZ vide their letter dated 08.04.2022 has requested for renew of approval for procurement of High Speed Diesel Oil at duty free rate from HPCL, Visakhapatnam refinery for plant DG set in case of power failures and avoid downtime for production and informed that their monthly consumption is 10 KL.

It is to submit that the unit has been granted permission vide this office letter dated. 30.05.2022 for procurement of 60 KL of HSD for a period of six months i.e from 17.05.2022 to 16.11.2022.

The Specified Officer, Brandix SEZ vide letter dated: 14.12.2022 has submitted consumption details for the period from 17.05.2022 to 15.11.2022 wherein it is informed that the unit has procured 12 KL of HSD without payment of duty during the above period. During the said period they have utilized 7.2 KL of HSDO out of 16.6 KL (Opening Balance 4.6 KL + Procured 12 KL)) and as on 16.11.2022 the closing balance of HSD is 9.4 KL.

The request of the unit for procurement of 60 KL per month of HSD for further period of six months is placed before the Approval Committee for considerations.

<u>Agenda Item No.19</u>:- Request of M/s. Natco Pharma Limited, unit in Ramky Phama SEZ for Procurement of High Speed Diesel oil for undertaking authorized operations – Reg.

M/s. Natco Pharma Limited, unit in Ramky Pharma SEZ has submitted an application for procurement of HSD for a quantity of 300 KL for a period of six months. They have informed that for continuous operations of boiler to generate steam and other equipment during power cuts they require to operate DG sets for which the High Speed Diesel Oil is required. They have submitted the diesel Consumption details for the period from 01.05 2022 to 31.10 2022 duly certified by the Specified Officer, Ramky Pharma SEZ.

The Specified Officer, Ramky Pharma SEZ has certified that the unit has procured HSD of 156 KL and utilized 164.223 KL (which includes the earlier balance) for the period from 01.05 2022 to 31.10.2022 and the balance is 16.8 KL. Their O.B as on 01.05.2022 was 25.014 KL.

It is to submit that M/s. Natco Pharma Limited has been permitted for procurement of HSD for a quantity of 75 KL per month for a period of six months i.e from 01.06.2022 to 30.11.2022 for undertaking authorized operations vide this office letter dated 02.06.2022.

The request of the unit for procurement of 300 KL of HSD for further period of six months is placed before the Approval Committee for consideration.

<u>Agenda Item No.20</u>:- Request of M/s. Biocon Limited, SEZ Co-Developer - Permission for enhancement of quantity of Diesel from 24 KL for the period of six months to 24 KL per month - Reg.

M/s. Biocon Limited, SEZ Co-Developer was granted permission for procurement of HSD for a quantity of 24 KL for a period of six month i.e. from 01.04.2022 to 30.09.2022 vide this office letter dated.30.05.2022.

Now the unit vide letter dated 19.12.2022 has informed that they had obtained permission for procuring HSD 24 KL per month from 01.04.2022 to 30.09.2022. Before obtaining the permission to procure diesel (HSD) they had presumed that both boilers will be operated. Based on such assumptions, they have obtained permission to procure 24 KL per month. However, they could not start the coal/Briquet boiler within the timelines due to delay in qualification of coal boiler & vendor installation issues. Hence, they could use only the diesel boiler to generate steam required to start trial and validation batches in the fermentation block.

Further, they have informed that since their plant is yet to commence regular production and running on trial basis, they could not arrive at the actual quantities of fuel (HSD) required to operate during the trial period. Once they reach the stage of commercial production, they will be in a position to assess the actual requirement. In this scenario, against the approval for 24KL HSD per month for 6 months (Apr-Sep'22) total 144 KL, they procured 372 KL HSD from Apr 2022 to Sep 2022 (228 KL in excess). Since there are multiple activities taking place, they have lost focus of HSD permission limits for procurement. It is humbly requested to condone the same. Further, from October to November 2022, we have procured 96 KL, we humbly request your good self to condone the omission and commissions in this regard.

Hence, it is requested to ratify the excess procurement & consumption of HSD used for Boiler to generate steam. And requested for approval to procure enhanced quantity of HSD of 720 KL for Six Months.

In this regard, the Specified Officer, Ramky SEZ vide letter dated: 16.12.2022 has informed the following:-

- 1) M/s Biocon Ltd, SEZ Co-Developer, Ramky SEZ, have informed vide their letter dt:15.12.2022 that they have obtained permission from the Development Commissioner (through UAC) for procurement of HSD without payment of duty/tax for authorised operations. As per the permission they can procure 24 KL/ month, for the period from April 2022 to Sept 2022.
- 2) In this connection, they have submitted that, theirs is a new unit and is on trial run and are yet to commence commercial production. Because of this and also due to multiple activities being carried out simultaneously in their unit, they have lost focus and procured more than the quantity permitted (total procured quantity is 372 KL in- which excess quantity is 228 KL) for the period from Apr-22 to Sep-22; Also procured 96 KL for the period from Oct-22 to Nov-22) and requested to ratify the excess procurements. They also informed that-
- i) they have facility of two boilers one operated on HSD and the other on Coal / briquettes;
- ii) the original request for HSD was made thinking that, both the boilers will be in operation from April 2022 onwards. But the coal boiler was commissioned after necessary quality checks and State government approvals in the month of November 2022; and
- iii) the HSD boiler only had to be used throughout the period, thereby causing excess consumption.
- 3) For the further period, from Dec-2022 to May-2023, they requested for HSD procurement of 720 KL(120KL/month).
- 4) In this connection, the documents relating to HSD procurement, the records maintained by the unit for procurement and utilization have been verified. As per the documents furnished by the unit, the coal boiler was put to use during November, 2022 after the certification of Director of Boilers. Since the findings as per the documents are in line with the submissions made by the unit, the request of the unit for ratification of excess procurements and approval for future procurements may be considered.

The request of the Co-Developer for ratification of excess procurements and approval of enhancement of quantity of Diesel from 24 KL to 372 KL for the period of six months is placed before the Approval Committee for considerations.

Agenda Item No.21:- Request of M/s. Therapiva Pvt. Limited a unit in M/s Ramky Pharma City (I) Ltd SEZ, Parawada, Visakhapatnam for extension of the LOA for another one year i.e. upto 18.08.2023.

M/s. Therapiva Pvt. Limited has requested for extension of the LOA for another one year i.e. upto 18.08.2023. The Unit has been advised to submit the Chartered Engineer

Certificate relating to implementation of the project. The unit vide their letter dated: 05 <sup>th</sup> September,2022 has informed that they have not taken steps for implementation so far. But eager to implement the project and requested to extend the LOA for another one year.

Based on the request of the unit, the Specified Officer, Ramky Pharma City SEZ has been requested to inspect the premises of the unit and to furnish the Inspection Report. In response, the Specified Officer, Ramky Pharma City SEZ vide letter dated: 16.09.2022 has informed that the site was inspected and observed that the unit has not taken any steps for implementation of the project and the site is lying vacant.

Simultaneously, the Developer, Ramky Pharma City SEZ has also been requested to furnish the status of the unit. In response, the Developer, Ramky Pharma City SEZ vide their letter dated: 21.10.2022 has submitted the following:

- 1) Regarding the present status of the Unit (M/s. Therapiva Pvt. Ltd) for the purpose of considering the extension of the LOA granted, earlier to the unit vide its request letter dated; 05.09.2022 which was not marked to them. In this context, it is pertinent to mention that M/s. Visakha Pharmacity Limited (Previously M/s Ramky Pharma City (India) Limited) (from here on referred as "VPCL") has issued a Provisional Allotment to Therapiva vide letter dated: 19.05.2021 in which certain conditions were imposed for taking the transaction forward. In fact, such provisional allotment was for a period of 2 months from 19.05.2021 which expired on 18.07.2021.
- 2) As the matter stood thus, Therapiva has failed to achieve/comply with certain conditions of the Provisional Allotment letter which resulted in non-execution of a registered lease deed in favour of Therapiva. Further, Therapiva has failed to commence any physical works/activities in the allotted plots bearing No. 120 & 121 Part admeasuring Ac. 12.135 Cents. Therefore, in view of such failures of Therapiva in adhering to the conditions of the provisional allotment coupled with the fact that such provisional allotment has expired, VPCL has allotted the said land in favour of M/s. Granules India Group on 22/09/2022.

The issue is placed before the UAC for information and orders.

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