

AGENDA FOR 119th UNIT APPROVAL COMMITTEEs MEETING FOR THE PRIVATE SEZs OF ANDHRA PRADESH REGION TO BE HELD ON 21.09.2020 AT 11.00 A.M. AT CONFERENCE HALL, ADMINISTRATIVE BUILDING, VISAKHAPATNAM SPECIAL ECONOMIC ZONE, DUVVADA, VISAKHAPATNAM.

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AGENDA FOR 119th UNIT APPROVAL COMMITTEEs MEETING FOR THE SEZs LOCATED IN PRIVATE SEZs OF ANDHRA PRADESH REGION TO BE HELD ON 21.09.2020 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 20.08.2020.

Agenda Item No. 02 : 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) vide letters dated 18.08.2020, 27.08.2020 and 01.09.2020 has requested for inclusion of the following additional products in the LoA..

S. No	Name of the product	API/Nutraceuticals / Intermediates	ITC code No.	Annual Production Capacity (In MTs)	Qty. To be manufactured in 5 years MT	NFE details for 5 years (Rs in Crores)
1	ASTAXANTHIN 2.5% DC/AFN-X	Nutraceuticals	32030090	05.00	25	65
2	VITAMIN D2 100 MB / SUN	Nutraceuticals	29362940	06.00	36	15
3	5-ACETAMIDO-N1,N3-BIS-(2,3-DIHYDROXYPROPYL)-2,4,6-TRIIODO ISOPHTHALAMIDE	Intermediates	29242990	250.00	1250	300
4	(3aR,4R,6R,6aR)-2,2-dimethyl-6-(2-oxo-4-(1H-1,2,4-triazol-1-yl)pyrimidin-1(2H)-yl)tetrahydrofuro [3,4-d] [1,3] dioxol-4-yl)methyl isobutyrate or MK-4482 Triazole-Stg-III	Intermediates	29335990	600.00	3000	600

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

The unit has submitted undertaking dated. 10.08.2020 and informed that products in respect of Sl. No. 1 & 2 meant for food and dietary supplements application. Products not intended for drug application. Divi's not claiming therapeutic value of products manufactured in nutraceuticals facility. Process flow, list of ingredients and fssai Licence are enclosed for above products.

Further the unit has informed that products in respect of Sl. No. 3 & 4 are intermediate products for which drug license is not required.

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. Alivira Animal Health Ltd. unit in M/s Ramky Pharma City SEZ for inclusion of additional product under broad-banding in LOA.

M/s. Alivira Animal Health Ltd. vide letter dated 08.09.2020 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	Nitroscanate Stage-I	INTERMEDIATE	4800 KGS	29420090
2	Nitroscanate Stage-II	INTERMEDIATE	7800 KGS	29420090
3	Nitroscanate Stage-III	INTERMEDIATE	6240 KGS	29420090
4	Nitroscanate Stage-IV	INTERMEDIATE	5703 KGS	29420090

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

Further, as the facility established is for manufacture of API's a number of products can be manufacture using the same facility depending on the demand for the product and order base. They will sell the intermediate also based on demand.

The unit has informed that they have attached Copy of Drug License No. 3928/P&B/2019 dt. 19.07.2019 and copy of Consent order for Establishment dated. 12.06.2019 and dated 17.03.2019. Annual capacity of production arrived based on validation products based CFO approval. **The above said Drug License is not found with this letter.**

Regarding the details of NFE projections in respect of new products the unit vide e mail dated. 15.09.2020 has informed that "for the product Nitroscanate API – we have LOA, however, there was some stock of intermediate stages lying with us, and our sister company got the orders to manufacture the same product, thus we are moving the available stock of intermediates to our sister company (Sequent Scientific Ltd). Thus we will not have any NFE for the same, however, we will pay the duty for the intermediates at the time of sale"

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 : Proposal of M/s Pals Plush India Pvt Ltd , unit in M/s Kakinada SEZ Limited for enhancement of production capacity in LOA.

M/s Pals Plush India Pvt Ltd vide letter dated 03.09.2020 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	Medical Apron Kits (Body Covers, face Shields, Shoe Cover)	3,50,000 Pieces	7,50,000 Pieces	Approved vide this office letter dated 28.05.2020 (copy enclosed)

The unit has informed that the duration will be 4 to 5 months and HS Code of the above product is 62041300.

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. 05 : Request of M/s. Hetero Drugs Limited (Unit-IX) a unit in Hetero Infrastructure Ltd. SEZ, Nakkapalli for inclusion of additional product under broad-banding in LOA.

M/s. Hetero Drugs Limited (Unit-IX) vide letters dated 11.09.2020 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	MEXILETINE HCL	API	29215990	KG	5(Tons)	1000

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. Due to this there will be no change in NFE projected and projected exports will remain same.

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. HMF07-14051/14/2020-TECH-DCA dt.15.06.2020 which are valid upto 19.10.2020.

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. 06 : Request of M/s. Granules Omnichem Pvt. Ltd. unit in M/s Ramky Pharma City SEZ for inclusion of additional product under broad-banding in LOA.

M/s. Granules Omnichem Pvt. Ltd vide letter dated 10.09.2020 has requested for inclusion of the following additional products in the LoA:-

S.No	Name of the Product	Category of Business	Capacity (Kgs / Per Month	HSN Code of Product
1	Quetiapine lactam (SER-2)	Intermediate	135	2915210090
2	Methyl 3,4 Dihydro – 2H Pyrano {2,3-C} Pyridine-6-Carboxylate (GPE)	Intermediate	96	293499900

The unit has submitted a Declaration stating that Drug License is not required for above intermediate products. The unit has also submitted the flow chart of the product.

Further it is also noticed that unit has enclosed the details of NFE projections in respect of above new 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. 07 : Request of M/s.Divi's Laboratories Limited (DCV SEZ Unit), a unit in M/s.Divi's Laboratories Limited SEZ, Visakhapatnam for inclusion of R&D Services in the LoA.

M/s.Divi's Laboratories Limited (DCV SEZ Unit) vide letter dated 11.09.2020 has requested for inclusion of the following R&D Services in the LoA.

The unit has proposed for the inclusion of R&D Services (process Development Services, pilot & Validation Studies for Active Pharma Ingredients and fine Chemicals). The unit has informed that they are getting regular requests from their multi National customers to conduct above services at their facility. The 'Contract research' within R&D services are provided under different specializations like process development, Chemical Hazard Evaluation, analytical services and the product scale up services. The inclusion of these services will be very useful to develop technical capabilities for out own employees along with the exposure to the latest developments in the field of medicine. In the process, our country can earn substantial Foreign Exchange also. They expect approximately Rs. 20 to 30 crores through R&D contract services in year. It will be approximately 100 Cr. NFE earnings for the coming next five years.

The unit has started Commercial Production on 20.03.2020. The details of the cumulative Exports, Import and NFE from 20.03.2020 to 10.09.2020 are given below:-

Financial Year	Cumulative Exports Cr. (Rs.)	Cumulative Imports Cr. (Rs.)	NFE Cr.
2020-2021	72 Cr.	30 Cr.	42Cr.

Further the Unit has informed that the majority of their Multi National Customers, who are regularly buying APIs from them, looking at their technical capabilities, are proposing for extending the R&D services also to them. They are ready to share the confidential information and technical capabilities to Develop new drugs at their facility. They have furnished list of availability of technical manpower and availability of required equipment.

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. 08 : Request of M/s. Brandix India Apparel City Pvt. Ltd. SEZ for Permission for Central Kitchen Built-up Space Grant on lease in the PZ Area – Reg.

M/s. Brandix India Apparel City Pvt. Ltd. SEZ vide letter dated. 02.07.2020 has requested for permission for grant Central Kitchen Built-up Space on lease in the Processing Area and submitted copy of Lease Agreement (unregistered).

In this connection, the Developer has informed that Brandix India Apparel City Pvt. Ltd. as a Park employee over 22,000 including more than 18,000 women, who come from close to 600 villages within a radius of 50 kms. Units within the Park have requested BIAC to set-up Central Kitchen for their employees and as a result, BIAC approached Touch Stone Foundation (aakshya Patra's associates), Visakhapatnam to operate and maintain the Centralized Kitchen within BIAC in order to supply food.

In this regard, it is to submit that this office vide letter dated.22.03.2019 has been granted approval for Import and procurement of equipments/goods for construction of centralized kitchen at their SEZ on the basis of authorized operations.

The request of the Developer for permission for grant Central Kitchen Built-up Space on lease in the Processing Area is put up for kind perusal and order please.

The request of the Developer for permission for Central Kitchen Built-up space grant on lease in Processing Area, it is to submit that in terms of SEZ Rules 2006, Rule 11 (5), Provided that the Developer may, with the prior approval of the approval Committee, grant on lease land or built up space, for creating facilities such as canteen, public telephone booths, first aid centres, crèche and such other facilities as may be required for the exclusive use of the unit.

Accordingly, the proposal is placed before UAC for consideration.

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