

AGENDA FOR THE 122nd UAC MEETING (VSEZ UNITS) SCHEDULED AT 1100 A.M ON 24.11.2020 ON VIDEO CONFERENCE UNDER THE CHAIRMANSHIP OF DEVELOPMENT COMMISSIONER,VSEZ, SHRI A.RAMA MOHAN REDDY, IFS, FROM HIS CHAMBERS IN THE ADMINISTRATIVE BUILDING, DUVVADA, VSEZ

Agenda item No.1.

Ratification of the minutes of the UAC meeting for VSEZ units held on 28.10. 2020

Agenda item No.2

M/S.Akrivis Health Care Pvt.Ltd intended to set up a unit for “Trading in Personal protective equipment (PPEs) include items such as gloves, face shields masks, safety glasses and shoes, earplugs or muffs, hard hats, respirators, or coveralls, vests, full body suits etc., and the UAC on 28.10.2020 approved for the same except for “Gloves” and directed the unit to submit revised figures of Exports, import, NFE in line with their present proposal for trading activity.

The company vide their letter dt.12.11.2020 submitted revised activity i.e., for “ Consultancy and Trading of Personal protective equipment (PPEs) , Medical equipment and supplies (as per Annexure) ” instead of the earlier proposed activity as mentioned above and submitted revised figures of exports, imports and NFE for trading activity .

Details of the proposal is as follows:

	Proposal	Setting up a unit in VSEZ, Duvvada, Visakhapatnam for
2	Name and address of the Company	M/S.Akrivis Health Care Pvt.Ltd., 8-13-6-4, Plot No.49, Jogavanipalem, Gajuwaka, Visakhapatnam
3	Item of Manufacture / Nature of activity	Consultancy and Trading of Personal protective equipment (PPEs) , Medical equipment and supplies (as per Annexure for 165 items)
4	Capacity Annual	N.A.
5	ITC HS code	Not submitted
6	Status of the concern	Ltd., company
6	Investment	Investment in P& M – Nil
7	Capital goods(for 5 years)	Nil
8	Raw materials, Components, Consumables etc packing material, fuel etc for 5 years.	41,035.16 lakh (indigenous) 60.32 lakh (import)

9	Details of source of finance	Stated self/loans
10	Requirement of built up space/ open land	100 sq. mtr.
11	Requirement of water	1.00 kilo ltr per month
12	Effluent treatment	not required (as stated)
13	Employment	Men:2 Women: 5
14	Requirement of power	1 KVA
15	FOB value of exports for 5 years	Rs.164,381.91 lakh
16	Foreign exchange out go for the first five years	Rs.60.32 lakh
17	Net foreign exchange earnings for the first five years	Rs.164321.59 lakh
18	Marketing	As per project report M/s.Akrivis Health Care is authorized by Q-Nord-Qatar Nord a Trading Company in Qatar to purchase 500 million 3 M health care particulate respirator and surgical mask 1860 on its behalf. An MoU with M/s.Tradewind Global Supplies(OPC) Pvt.Ltd.,
19	Foreign technology if any	no
20	Foreign Investment	no
21	Nature of Foreign Collaboration	N.A.
22	Income Tax Returns of the Company	Submitted for two FY 2017-18 and 2018-19
23	Income Tax Returns of the Directors:	Submitted in respect of Mr.Sarat babu Janipalli for the AY 2017-18 and 2018-19

Details of the Company as per application:

The Company was incorporated on 10.10.2017 . The Company is into Health care products from R& D stage to commercialization. Their current research comprises of Biobanking, Stem cells and exosomes for Regenerative medicine, screening model system,s development and manufacture of COVID -19 diagnostic kits.

- They have MoU with a Canada based investment body for a funding of 5 million USD to development exosomes-based product line.

Have association with an Israel based technology firm to develop next level COVID-19 diagnostic kits to quantify human individual immunity levels through multiple assay markers during the disease.

Authorized distributors for Hindustan Lever Ltd., HLL Life care Ltd., for the sale of "MakeSure COVID 19 IgM/IgG Rapid in vitro Diagnostic Kit.

M/s. Akrivis is having plans for trading of PPEs.

Profile of the Directors as per Project Report:- There are two Directors

1. Dr.Sarat Babu Janipalli, is MS in ENT with more than ten years of practice as a head and neck surgeon. His passion towards health care sector made him step ahead as Researcher and Entrepreneur. His strong interest in interdisciplinary science and research made him fund successful research projects for translational, and regenerative medicine. He has global reach as a clinician and entrepreneur and currently working for game changing COVID-19 pandemic related products to India and other countries.
2. Mr.Sampath Kumar Janipalli works as an IT Consultant with formula one and automotive companies. He worked with automotive majors in Japan, South Korea, Germany, and UK. He has done B.Tech(IIT-Madras) and PGDM(IIM-Madras) and PGDM(IIM-Ahmedabad) and currently works in the UK.

The proposal is submitted before the UAC in terms of Rule 17 and 18 of SEZ, Rules, 2006 for consideration.

Agenda items No.3

Request of M/s.Reddy's Laboratories Ltd., Formulation unit IX, Plot No. Q1 toQ5 for inclusion of New products in their LoA – reg.

The unit was issued LoA dt.08.06.2012 for manufacture of pharmaceutical tablets, capsules, injections and commenced production w.e.f.1.11.2017. The unit intends to add the following new products in their LoA:

Sl.No.	Item of manufacture	Injections/Vial	ITCHS	Exhibit Batches quantity in Nos.
1	Brimonidine Tartrate Ophthalmic Solution 0.025% (Fill Volume 7.5 ml)	Ophthalmic Suspension	30049099	200000 bottles
2	Brimonidine Tartrate Ophthalmic Solution 0.025% (Fill Volume 2.5 ml)	Ophthalmic Suspension	30049099	600000 bottles
3	Brimonidine Tartrate Ophthalmic Solution 0.025% (Fill Volume 0.4 ml)	Ophthalmic Suspension	30049099	500000 ampoules
4	Dexamethasone Sodium Phosphate Injection USP 4 mg/ml	Injection	30041090	540000 Nos.

5	Dexamethasone Sodium Phosphate Injection USP10 mg/ml (Fill volume : 1 ml)	Injection	30041090	500000 vials
6	Dexamethasone Sodium Phosphate Injection USP10 mg/ml (Fill volume : 10ml)	Injection	30041090	50000 vials

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

The unit has submitted process chart of manufacture of the above drugs.

The unit for the items from Sl.No.1-3 above submitted permission in CT 14 to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis and not for clinical trial or bioavailability or bioequivalence study issued by Central Drugs and Standard Control Organization. License No.42-2/HZ/2019-20/945/CT-14 /Permission/1077 dt.21.07.2020 for 3 years period from 21.07.2020 . In respect of the items No.4-6 above, the unit submitted Test license in form 29 vide L.Dis No.HMF07-14-51/384/2020-TECH-DCA dt.18.08./2020, dt.24.08.2020 for a period of 3 years from the date of issue.

The request of the unit was earlier submitted before UAC on 28.10.2020 and the UAC deferred the proposal, for non-representation from the unit in the meeting to clarify the points raised by member of the UAC, to the scheduled meeting on 24.11.2020 .

The proposal is placed in this meeting for consideration.

Agenda items No.4

Request of M/s.Reddy's Laboratories Ltd., Formulation unit VII, Plot No. P1 to P9 for inclusion of New products in their LoA – reg.

The unit was issued LOA dt.23.03.2005 for manufacture of injectables /injections(pre-filled Syringes, vials & cartridges as amended from time to time and had commenced production on 22.4.2010 as per records. The unit vide their letter dt.15.10.2020 requested for inclusion of New product for manufacture of 'Paclitaxel protein-bound particles for Injectable suspension(albumin bound), 100mg /vial under ITCHS 30049041 at an annual capacity of 2,70,000 kg for an estimated value of Rs.1836/- under broad banding in their LoA.

The unit submitted flow chart for manufacture of the above product, and declared that the item is not a restricted/prohibited item under ITC HS.

The unit submitted copy of approval given by Drug Control Administration, Guntur vide L Dis.No.184/P&B/2020 dt.13.02.2020 under License in Form 29 for the purpose of Examination, test for chemical and instrumental analysis. This product manufactured against this Test Licence are not for any commercial use and shall be used for Bio/clinical studies subject to the grant of BE/CT permission from the DCG(I) Office. It was stated that in case of

Narcotics Psychotropic Drugs, the Narcotic Commissioner of India, Gwalior shall be approached by the unit in so far as the provisions of the NDPS act and the Rules are concerned.

The proposal of the unit for inclusion of the above mentioned product in their existing LoA is submitted for consideration by the UAC, please.

Agenda item No.5

Ratification of the permission granted by Development Commissioner, VSEZ consequent to submission of countries with who the unit intends to transact for 'Courier services' in terms of Rule 76 of SEZ Rules. 2006, in A/O M/s. DOLE Logistics.

The unit was issued LoA dt.29.09.2018 for 'warehousing and Trading Services'. The unit commenced operations on 30.09.2020 as per records. The unit vide their letter dt.13.10.2020 requested for inclusion of additional activities in their LoA i.e., "courier services" under SEZ Rule 76.

The request of the unit was placed before UAC on 28.10.2020 and the UAC directed the unit to submit the countries of export /import in respect of the proposed Courier Services for consideration. Vide minutes of the meeting dt.28.10.2020.

The unit vide their letter dt.5.11.2020 informed the countries with who they intend to transact are viz., UK, USA, UAE, Singapore, Canada, Hongkong, Germany, Netherland, South Africa and Australia and also the unit declared the HSN code 98049000 for the said services.

The same was put up on file, and as approved on file, a letter dt.12.11.2020 was issued to the unit. The same is placed before UAC for ratification.
