

AGENDA FOR 111th UAC MEETING (VSEZ UNITS) SCHEDULED AT 1100 A.M ON 29.11.2019 AT 11.00 A.M UNDER THE CHAIRMANSHIP OF DEVELOPMENT COMMISSIONER,VSEZ, SHRI A.RAMA MOHAN REDDY, IFS, IN THE CONFERENCE HALL OF ADMINISTRATIVE BUILDING, DUVVADA

Agenda item No.1.

Ratification of the minutes of the UAC meeting for VSEZ units held on 25.10.2019

Agenda item No.2

Confirmation of permission granted for inclusion of Eribulin Mesylate Injection 1 mg/2ml in the LoA M/s.Reddy's Laboratories Ltd., Formulation unit VII, Plot No. P1 to P9 vide their letter dt.21.08.– reg.

The proposal of the unit for inclusion of additional product i.e., “Eribulin Mesylate Injection 1 mg/2ml under broad banding was discussed in the UAC meeting held on 25.9.2019 and it has been decided to defer the proposal for want of clarification from the unit with regard to annual capacity of “ 2 million each “ of the said product w.r.t. Examination, Test or analysis license.

The unit vide their letter dt.1.11.2019 informed that the 2 million capacity (vials) is the annual capacity for the purposes of both the Examination, Test or analysis and for the finished product.

Accordingly, the request was considered by the Office on file and the declared annual capacity of 2 million Vials of Eribulin Mesylate Injection 1 mg/2ml has been taken on record and permission for inclusion of the product in the LoA of the unit has been granted, vide letter dt.13,11.2019.

The permission accorded by the office has been placed before UAC for ratification.

Agenda item No.3

Request of M/s.Lee Pharma Ltd., VSEZ for inclusion of ‘FILBICART capsules’ in the LoA – reg.

The unit vide their letter dt.11.11.2019 requested for inclusion of additional product ‘FILBICART capsules’ (ICHS 30049099) at an annual capacity of 25.00 lakh capsules ‘in the LoA and submitted details of raw material, manufacturing flow chart and also submitted Licence copy issued by FSSAI, Govt. of Andhra Pradesh vide Licence No.10116028000399 dt.5.11.2019.

The request of the unit is placed before UAC for consideration.

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Agenda item No.4

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

The unit was issued LoA dt.23.03.2005 for manufacture of pharmaceutical tablets, capsules, injections and commenced production w.e.f.22.4.2010 . The unit intends to add new product ' Capecitabine Granules 81.57 %w/w under ITCHS 30049-99 at an annual capacity of 1200 kg valued Rs.7,72,00,000/- and declared that the item is not a restricted/prohibited item under ITC HS.

The unit submitted process chart for manufacture of the above drug. The technical write up states that the drug is used for treatment of Colorectal Cancer and Breast Cancer.

The unit has not submitted any permission/Licence from Drug Control Authority for manufacture of the above product.

The request of the unit is placed before UAC to consider inclusion of new product in their LoA under broad banding in terms of Rule 19(2) of SEZ Rules, 2006.

Agenda item No.5

Request of M/s.Sai RP Enterprises, engaged in trading activity in VSEZ, vide their letter dt.21.10.2019 requested for inclusion of additional products viz., Sweets , tea/coffee powder in the Letter of Approval (LoA) for supplying the same to duty -free shops in India and abroad.

The unit vide their letter dt.11.11.2019 requested that pending approval of UAC the item, Sweets may be included in the LoA to enable them to meet the timeline to supply to their clients by 15.11.2019.

In view of the exigency expressed by the unit, the request of the unit for inclusion of 'sweets' has been considered on file and provisional permission has been granted for the said inclusion subject to ratification by the UAC.

In view of the above, the request of the unit for inclusion of Tea/coffee powder under ITCHS 21011190/21012010/21012090/21013090 in the LoA is placed before UAC for consideration. The provisional permission granted for inclusion of 'sweets' under ITCHS 21069099 has also been placed before UAC for ratification.

Table agenda (VSEZ units) for the UAC meeting scheduled on 29.11.2019

Request of M/s.Sai RP Enterprises for inclusion of 'Jute Bag having HS code 42022220 and Cosmetics having HS code 33030020/33049910/34011900 in the LoA – reg.

M/s.Sai RP Enterprises, VSEZ has been granted LoA dt. 12.07.2016 for trading activity and have been adding additional products in their LoA from time to time, under broad banding.

The unit vide their letter dt.25.11.2019 requested for adding additional products, Jute Bag having HS code 42022220 and Cosmetics having HS code 33030020/33049910/34011900 in their LoA under broad banding stating that they would procure the products from DTA and supply them to Duty free stores at International Airports in India and out of India.

The request of the unit for inclusion of additional product, is placed as a table agenda for consideration under broad banding in terms of Rule 19(2) of SEZ Rules, 2006.