AGENDA FOR THE APPROVAL COMMITTEEs MEETING FOR THE VSEZ& PRIVATE SEZs OF ANDHRA PRADESH UNDER THE CHAIRMANSHIP OF SHRI SRINIVAS MUPPAALA, IRSME, ZONAL DEVELOPMENT COMMISSIONER TO BE HELD ON 24.11.2023 THROUGH HYBRID MODE AT 11.00 AM

VSEZ – ANDHRA PRADESH

Agenda Item No.AP-175.01 :- Ratification of the Minutes of the meeting

The minutes of the UAC meeting 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.

Agenda Item No.AP-175.01 :- Request of Dr. Reddy's Laboratories Ltd. FTO-IX Plot No. Q1 to Q5 for inclusion of new product in the LoA – reg.

Dr. Reddy's Laboratories Ltd. FTO-IX has requested for inclusion of following products in the existing LoA.

S.No.	Item of manufacture	Injectable	Approx. Annual Capacity Vials	Probable ITC (HS)
1	Trace elements Injection 4, USP (Each mL provides 1000 mcg of Zinc equivalent to 2470 mcg of Zinc sulfate (equivalent to 4398 mcg Zinc sulfate heptahydrate USP), 60 mcg of Copper equivalent to 150 mcg of Cupric sulfate (equivalent to 235.74 mcg of Cupric sulfate pentahydrate USP), 3 mcg of Manganese equivalent to 8.22 mcg of Manganese sulfate (equivalent to 9.2 mcg of Manganese sulfate monohydrate USP) and 6 mcg of Selenium equivalent to 9.8 mcg of Selenious acid USP)	Injections	150000	30049099
2	Selenious Acid Injection USP, 12MCG/2 ml(6 MCG/ML)	Injections	75000	30049099

The unit has informed that they have been regularly including new products for manufacture in the LoA in addition to the products already included.

The unit has submitted **Test License in Form-29** issued by Drug Control Authority of the above products for a quantity of 150000 & 75000 vials exclusively **for the purpose of R & D/ formulation development/manufacturing of Exhibit batches**.

The unit has informed that the Drug licenses are for Testing and Analysis purpose and hence there will be no commercial sale of the products until the same is commercialised. The unit has informed that there will be no change in Annual capacity and NFE.

Further, the unit informed that the above products are for manufacturing in formulation plant and no need of PCB license as PCB license issued single time for formulation units.

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

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

The unit has furnished the copy of Drug Licenses in respect of the above products vide File No. HMF07-14051/1073/2023-ADMIN-DCA dated 14.06.2023 & No. HMF07-14051/1098/2023-ADMIN-DCA dated 15.06.2023 which shall be in force for three years from the date of issue.

As the products proposed falls under the category of Formulation hence CFE/CMP is not applicable in the instant case.

The above product with ITC HS code 30049099 is free for export as per Schedule 2-Export Policy, ITC(HS)2018.

In terms of Rule 19(2), approval committee may also approve 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.

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