

Minutes of the 49th (forty-ninth) meeting of the Approval Committee for sector specific Pharmaceuticals – Special Economic Zone developed by M/s. Zydus Infrastructure Pvt. Ltd., held on 22-01-2019 at 1700 hours, under the Chairmanship of Dr. Amiya Chandra, ITS, Development Commissioner, Kandla Special Economic Zone, in the conference room of Zonal DC's office, at KASEZ City Office, Ahmedabad.

List of participants is annexed as Annexure-I

Approved minutes of the previous meeting were confirmed by the Approval Committee.

A) Other proposals:-

49-A-01) Monitoring of Performance of SEZ units in Zydus - Pharma-SEZ, in respect of performance up to the monitoring year 2017-18.

In terms of provisions of Rule 22 of the Special Economic Zones Rules, 2006, the operational SEZ units are required to submit their respective Annual Performance Reports (APR) in prescribed format i.e. Form-I to the Development Commissioner and the same needs to be placed before the Approval Committee for consideration. The units have to submit their APRs duly scrutinized and certified by Chartered Accountant appointed by the unit. Performance of the units is to be monitored by the Office of the Development Commissioner. The Office of the Development Commissioner has appointed independent Chartered Accountant for detailed scrutiny of these APRs. Chartered Accountant appointed for the purpose has scrutinized these APRs.

The Approval Committee has reviewed the CA certified and internally scrutinized APRs of 09 (nine) SEZ units as on 31-03-2018 i.e. up to monitoring year 2017-18 for each of block of 5 years (60 months), and the net result is as under:-

Sr. No.	Name of the SEZ unit	Date of commencement of operation	Months of operation for 1 st Block	Months of operation for 2 nd Block	Cumulative NFE earned (Rs. in lakhs)
A					
SEZ units completed operations for 05 (five) years and more :-					
01)	Alidac Pharmaceuticals Ltd. (formerly Zydus BSV Pharma Pvt. Ltd.).	12-08-2011	60 (already reviewed)	19	16761.15
02)	Intas Pharmaceuticals Ltd.	07-05-2010	60 (already reviewed)	35	217790.11
03)	Piramal Enterprises Limited (Plot No. 18)	01-04-2009	60 (already reviewed)	48	27359.78
04)	Piramal Enterprises Limited (Plot No. 19) (formerly Oxygen Bio Research Pvt. Ltd.)	20-05-2009	60 (already reviewed)	46	11710.64
05)	Fisher Bio Pharma Services (India) Pvt. Ltd.	15-10-2008	60	54	13177.47



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06)	Mylan Laboratories Ltd., (formerly Jai Pharma Ltd., and Famy Care Limited) – manufacturing	05-05-2009	60 (already reviewed)	47	65148.83
07.	Amneal Pharmaceuticals Pvt. Ltd.,	06-06-2013	58	-	65238.46
08.	Zydus Hospira Oncology Pvt. Ltd.,	18-05-2009	60 (already reviewed)	47	52011.57
09.	Cadila Healthcare Limited	04-06-2016	23	-	61.85
B	SEZ unit completed operations for less than 01 (one) year:-				
01.	Biotech Visioncare Pvt. Ltd	22-06-2017	9	-	(-) 3989.09

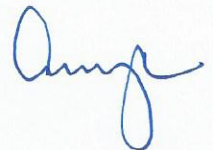
There is one case of negative NFE, however the SEZ unit has not completed the required time wherein penal action is required in fact it is less than one year and review was also not required in terms of SEZ Rules, 2006.

S) Supplementary case:-

49-S-01) Proposal of M/s. Cadila Healthcare Limited, Ahmedabad, for setting-up of new manufacturing unit in Zydus – Pharmaceutical-SEZ, Ahmedabad.

Shri Sanjeev Sharma, VP, and Shri Sanjay Singh, GM under authority of the applicant company appeared before the Approval Committee for personal interview. They explained their proposal for setting-up new second manufacturing unit in Zydus – Pharmaceutical –SEZ, Matoda, Ahmedabad for manufacture and export of a) Pharmaceutical medicine for animals, veterinary products, topical solutions in liquid form; and b) Pharmaceutical medicine for animals, veterinary products oral tablets, chewables. The applicant company is engaged in the business of manufacturing and exporting pharmaceutical products. A brief detail of the proposal is as under:-

- FOB value of export for said project for 05 (five) years period is projected as Rs. 18545.00 lakhs, with outgo of foreign exchange at Rs. 6169.00 lakhs resulting in NFE of Rs. 12376.00 lakhs (66.73%).
- The proposed project envisages investment of Rs. 23.69 crores and employment for 78 people.
- The representatives of the applicant company confirmed that they shall be exporting their entire production and there will be no DTA clearance of proposed products.



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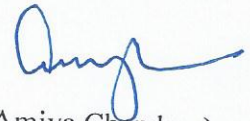
The Approval Committee asked the applicant company to enumerate the required regulatory approvals required for the proposed products, on this specific query they vide their letter dated 22-01-2019 stated that the following regulatory approvals are required for manufacturing and export of veterinary products:-

- 1) Manufacturing license local FDA (Food & Drugs Control Administration, Gujarat State);
- 2) Product permission local FDA (Food & Drugs Control Administration, Gujarat State);
- 3) Plant should be approved by CVM (Centre for Veterinary Medicine);
- 4) Product should be approved under NADA (New Animal Drug Application) of ANADA (Abbreviated New Animal Drug Application) USFDA (US Food and Drug Administration);
- 5) NOC from drug Controller CDSCO (Centre Drug Standard Control Organization) for Export & Import.

- The Developer (ZIPL) vide PLOA/letter dated 19-12-2018 has earmarked the required premises/space (Plot Nos. 12 & 13) in the SEZ for the proposed project.
- The Approval Committee emphasized that the applicant has to furnish a copy of the registered Lease Deed to the Development Commissioner within six months from issuance of the Letter of Approval for the allotted premises in SEZ, as required in terms of Rule-18 (2) (ii) of the SEZ Rules, 2006.

The Approval Committee after due diligence and deliberation approved the current proposal, subject to standard terms and conditions, of the SEZ Rules, 2006, and the applicant shall get all mandatory/statutory Regulatory approval from all concerned authorities, including approvals/clearances from Environment and Pollution Control Authorities before commencement of manufacturing operations and exports.

The unit also submitted letter dated 22-01-2019 undertaking that they shall start manufacturing and export activities only after obtaining all regulatory approvals/permissions.



(Dr. Amiya Chandra)
Chairman of Approval Committee,
& Zonal Development Commissioner,
Kandla Special Economic Zone.

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The following members were present:-

ANNEXURE-I

01.	Dr. Amiya Chandra, ITS, Development Commissioner, Kandla-SEZ.	Chairman
02.	Shri Shashank Shende, JDC, SEZ cluster, Ahmedabad.	Nominee for the Director – SEZ, DOC, MOC&I.
03.	Shri Akshay S. C., Deputy DGFT	Nominee of the Jt. DGFT, Ahmedbad.
04.	Shri R. R. Gamit, DPO, Ahmedabad.	Nominee of the District Collector, Ahmedbad.
05.	Shri R. S. Patel, Manager (RM), DIC, Ahmedabad.	Nominee of the GM, DIC, Ahmedbad.
06.	Shri Kailash Bahuguna, COO, M/s. Zydus Infrastructure Pvt. Ltd.,	Representative of the Developer – Zydus.

