

Minutes of the 32nd (thirty-second) meeting of the Approval Committee for sector specific Pharmaceuticals – Special Economic Zone developed by M/s. Zydus Infrastructure Pvt. Ltd., held on 21-01-2016, at 1100 hours, under the Chairmanship of Shri Upendra Vasishth, ndc, Development Commissioner, Kandla Special Economic Zone, in the Office of the Development Commissioner, Kandla-SEZ, Ahmedabad.

List of participants is annexed as Annexure-I

A) Other proposals:-

32-A-01) Proposal of M/s. Jai Pharma Ltd., unit in Zydus- Pharma-SEZ for broad-banding of existing LOA for inclusion of additional items.

Shri Mitesh Solanki, Project Manager, and Shri Mahesh Patel, Assistant Manager (Commercial) under authority of the applicant company viz. M/s. Jai Pharma Ltd., appeared before the Committee and briefly explained their fresh proposal for broad-banding for inclusion of new items to existing LOA.

Before going into merits of the current proposal the Approval Committee emphasized that subsequent to the de-merger approvals granted by the Hon'ble High Court of Mumbai Order dated 24-04-2015 in Company Petition Nos. 210 and 211 of 2015, and various Competent Authorities, including this Approval Committee, it was made clear that M/s. Jai Pharma Ltd., shall conduct and operate its granted approvals from Plot Nos. 20, and 21 in the Pharma-SEZ developed by M/s. Zydus Infrastructure Pvt. Ltd. As per the approvals already granted, M/s. Famy Care Ltd., shall conduct and operate its approvals from Plot No. 23 of the Pharma-SEZ, and further advised M/s. Famy Care Ltd., to commence operation independently.

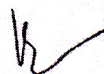
Approval Committee thereafter considered the broad-banding request of M/s. Jai Pharma Ltd., which was for inclusion of 06 (six) new pharmaceutical products, namely 1) Ribavirin Tablets and Capsule; 2) Pirfenidone Capsules; 3) Teriflunomide; 4) Amlodipine Besilate/Perindopril Erbumine; 5) Linezolid; and 6) Ondansetron Hydrochloride are falling under Chapter-30 of ITC (HS) Classification.

Approval Committee after due diligence approved the proposal for broad-banding, subject to normal terms and conditions of the SEZ Rules, and all other mandatory and statutory regulatory approvals required for the new pharmaceutical products.

32-A-02) Proposal of M/s. Biomedical Lifesciences Pvt. Ltd., unit in Zydus- Pharma-SEZ for broad-banding of existing LOA for inclusion of additional items.

Shri Mehul Asnani, Chairman, and Managing Director of the applicant company appeared before the Committee and briefly explained their fresh proposal for broad-banding for inclusion of new items to existing LOA.

Before going into merit of the proposal the Chairman of the Approval Committee briefed other Committee members about the background facts of the applicant/case. M/s. Biomedical Lifesciences Pvt. Ltd., were originally granted approval vide LOA dated 06-06-2008, however they had failed to commence commercial production within the stipulated and extended time limit. Thus, the said LOA dated 06-06-2008 was cancelled/treated as lapsed vide Development Commissioner's Order dated 22-03-2012. Thereafter, there was a long drawn litigation, adjudication proceedings, appeal etc. in the said case.



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Finally, the Board of Approvals for SEZ, decide the following in its 61st meeting held on 03-04-2014:-

'Minutes of the 61st meeting of the BoA for SEZs held on 3rd April, 2014'

Quote "(iv) Appeal of M/s. Biomedical Lifesciences Pvt. Ltd., a unit in pharmaceutical SEZ developed by M/s. Zydus Infrastructure Pvt. Ltd. at Ahmedabad, Gujarat against order of DC, KASEZ.

The Board heard the appellant. After examining the matter, the BoA set aside the order dated 10/13th January, 2014 of DC KASEZ and restored the LoP of the Appellant and allowed time for a period of one year to commence commercial production. The period of one year shall commence from the day the developer hands back possession of the said plot to the Appellant. The BoA also directed the DC KASEZ to ensure that the plot is returned to the appellant immediately." Unquote

In terms of the above direction of the BoA in its 61st meeting held on **03-04-2014**, the Developer (ZIPL), had complied with the said direction regarding handing back possession of plot to the Appellant/unit. The Developer (ZIPL), vide their letter dated 24-06-2015 informed handing over the possession of Plot No. 04 in SEZ to M/s. Biomedical Lifesciences Pvt. Ltd. w.e.f. **24-06-2015**. Thereafter the said applicant was informed by the DC, KASEZ, that their LOA dated 06-06-2008, as amended from time-to-time shall be valid for one year from 24-06-2015 till 23-06-2016 to commence commercial production in SEZ.

Approval Committee thereafter considered the broad-banding request of M/s. Biomedical Lifesciences Pvt. Ltd., which was for inclusion of 09 (nine) new pharmaceutical products, namely 1) Decaline PFS; 2) Hydrophobic; 3) Decaline Plus 7ml vial; 4) HA [a) Bio Hyalur, b) Bio Hyalur plus, c) Bio Hyalur MV, d) Bio Hyalur EV, e) Bio Hyalur HV, f) Bio Hyalur SV]; 5) HPMC [eye visc PFS]; 6) Octane PFS; 7) Octane Plus 7 ml; 8) Silicon Oil – 1000/5000 PFS; 9) Heavy Silicone Oil 1400. Approval Committee noted that each of the products is free for import and export under the ITC (HS) classification. However, the applicant was asked to furnish all types of other mandatory and statutory regulatory approvals for such products before commencement of production.

The Approval Committee has observed that this being sector specific pharmaceutical SEZ, only pharmaceutical products can be manufactured whereas the applicant has applied for broad-banding of following products which appears neither bulk drug nor pharmaceutical products:-

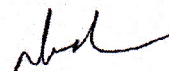
<u>Sr. No.</u>	<u>Name of product</u>	<u>Chapter No. of ITC (HS)</u>
01)	Hydrophobic	90
02)	Silicon Oil – 1000/5000 PFS	39
03)	Heavy Silicone Oil 1400	39

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The Approval Committee has informed to the applicant that how products other than pharmaceuticals can be produced in sector specific pharmaceutical SEZ. Shri Mehul Asnani has produced copy Notification No. S.O. 1468 (E), dated 06-10-2005 of the Ministry of Health and Family Welfare, Government of India stating that "Intra Ocular Lenses" is to be considered as drugs under Section-3, Clause (b), Sub clause (iv) of the Drugs and Cosmetics Act, and explained that all the items requested for broad-banding are related to Ophthalmic use and the same are very essential for treatment of eyes.

The Committee has observed that the Notification No. S.O. 1468 (E), dated 06-10-2005 issued by the Ministry of Health and Family Welfare, Government of India stating that "Intra Ocular Lenses" is to be considered as drugs. Thus, the Approval Committee concluded that the 9 (nine) items as above sought for broad-banding are related products connected to original approved items viz. "1) Flodable Intra Ocular lens; and 2) Flodable Lenses Kits" and as stated by the applicant the same is directly used for ophthalmic applications

Thus, Approval Committee after due diligence approved the proposal for broad-banding, subject to normal terms and conditions of the SEZ Rules, and all other mandatory and statutory regulatory approvals required for the new pharmaceutical products.



(Upendra Vasishth ndc)
Chairman of Approval Committee,
& Development Commissioner,
Kandla Special Economic Zone.

The following members were present:-

ANNEXURE-I

01.	Shri Upendra Vasishth, ndc Development Commissioner, KASEZ.	Chairman
02.	Shri Anand Jagtiani, JDC(i/c), KASEZ City Office, Ahmedabad.	Nominee for the Director – SEZ, DOC, MOC&I.
03.	Shri K. Madhusudan, Additional Commissioner of Income Tax, Ahmedabad-IV.	Nominee of the Commissioner of Income Tax, Ahmedabad-IV.
04.	Shri Umesh Kumar Garg, Assistant Commissioner of Central Excise, Ahmedabad.	Nominee of the Commissioner of Central Excise, Ahmedabad-II.
05.	Shri N. B. Nangas, ADGFT, O/O Jt. DGFT, Ahmedabad.	Nominee of the Jt. DGFT, Ahmedabad.
06.	Shri Kailash Bahuguna, CEO, Zydus Infrastructure Pvt. Ltd.,	Representative of the Developer – Zydus.