

Minutes of the 19th (nineteenth) meeting of the Approval Committee for sector specific Pharmaceuticals – Special Economic Zone developed by M/s. Zydus Infrastructure Pvt. Ltd., held on 21-09-2012, at 1615 hours, under the Chairmanship of Shri Mahendra Jain, IAS, Development Commissioner, Kandla Special Economic Zone, in the conference room of DC's Office, Dahej – SEZ, Ahmedabad.

List of participants is annexed as Annexure-I

A) Other proposals:-

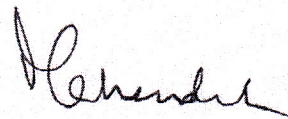
19-A-01) M/s. Fisher Bio Pharma Service (India) Pvt. Ltd; Zydus – Pharma – SEZ – Request for permission to return unused/partially used clinical trial patient kits from trial sites back into the warehouse in SEZ:-

Dr Pramod Kabra, Managing Director, of the applicant company appeared before the Committee and explained their approved Authorized Operation in the SEZ. They are into clinical trail i.e distribution of patient kits (clinical trial materials) for Phase-II and III stage clinical trial and its related R&D services in the SEZ. These distributed patient kits used, unused, partially kits are to be well documented and warehoused as per the approved norms of the Regulatory Authority (i.e. Director General of Health Services). The Committee noted that this is mandatory requirement and advised the applicant to follow the procedure set out by the Specified officer in this regard. And in case of any difficulty it may be brought up before the Approval Committee.

19-A-02) Submission of Half Year Progress Report by the Developer – Zydus Infrastructure Pvt. Ltd., for Pharma – SEZ, Ahmedabad:-

The Committee noted and taken on records the Half Yearly Progress Report for the period of October, 2011 to March, 2012, filed by the Developer. However, the Central Excise Department has reported that as per the said report there are un-used materials lying idle. The Committee directed that the Specified Officer to examine whether the goods are lying idle, un-utilized for the Authorized Operations, and in case the same are not used for Authorized Operation, action may be taken for recovery of duty on the un-used goods lying in the SEZ.

(Action: JDC, KASEZ)



(Mahendra Jain)
Chairman of Approval Committee,
& Development Commissioner,

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Kandla Special Economic Zone.
ANNEXURE-I

The following members were present:-

01.	Shri Mahendra Jain, IAS, Development Commissioner, KASEZ.	Chairman
02.	Shri A. K. Singh, Jt. DGFT, Ahmedabad.	Member
03.	Shri S. N. Patil, Joint Development Commissioner, KASEZ.	Nominee for the Director – SEZ, DOC, MOC&I.
04.	Shri D. H. Amin, GM, DIC, Ahmedabad	Member.
05.	Shri Reghuraman R. S., Superintendent (Tech)	Nominee for the Commissioner of Central Excise, Ahmedabad-II.
06.	Shri Kailash Bahuguna, COO –SEZ, Zydus Infrastructure Pvt. Ltd.,	Representative of Developer – Zydus.