

YEAR-WISE DETAILS OF APPLICATIONS REJECTED BY CDSCO (2012-2014)

Name of the Division:

Sr. No.	Name of the applicant	Type of Application	Dairy Number & Date of receipt of Application	Product Details	Date of rejection	Detailed reason for rejection
1.	M/s Bioreclamation	Import of Animal Serum Plasma for	FTS No. 59911 Dated 25/09/2014	Animal serum Plasma	12/9/2014	Not pertains to this Directorate.
2.	M/s. Wockhardt Ltd. Wockhardt Towers, BandraKurla complex, Bandra (East), Mumbai 400051	Correction in Form 10 due to typographical error	32140 dated 28/07/2014	Freeze dried Attenuated Hepatitis A vaccine	9/30/2014	There was no typographical error in Form 10.
3.	M/s Biocon Limited	NOC for import of naked vials of product in bulk containers for relabeling in India	21764 dated 21/05/2014	Recombinant Human Erythropoietin Injection	10/15/2014	Application is not fulfilling the requirements of Rule 32, Part IV of Drug and Cosmetics Rules 1945, also not falling under the category of patent and proprietary medicines reference to Chapter I [3 (h) (ii)- Definitions under the Drugs and Cosmetics Act 1940 and Rules there
4.	M/s Virbac Animal Health India Pvt. Ltd	Renewal of Registration Certificate and Import license	11200 dated 13/03/2014, 11203 dated 13/03/2014 & 34420 dated 12/08/2014	Oral Rabies vaccine Bait (Live attenuated rabies virus, SAG2 strain) for dogs	10/14/2014	Due to production constraints at manufacturing site, firm do not want to renew the RC.
5.	M/s Zoetis India Ltd., Mumbai	Endorsement of 5x10 ml presentation of Rabies veterinary vaccine	41481 dated 29/09/2014	Rabies veterinary vaccine	11/19/2014	Application is not as per the requirements of Rule 24A.

6.	M/s GSK Asia Pvt. Ltd.	Endorsement in RC	6200 dated 12/2/2014	bulk Unlabelled sealed vial of 13 vaccines	2/26/2014	Application is not fulfilling the requirements of Rule 32, Part IV of Drug and Cosmetics Rules 1945, also not falling under the category of patent and proprietary medicines reference to Chapter I [3 (h) (ii)- Definitions under the Drugs and Cosmetics Act 1940 and Rules there under. Further, after ministry approval firm
YEAR 2012 & 2013 - Nil						