

File No. X11026/181/14B
Directorate General of Health Services
O/o Drugs Controller General (I)
(Biological Division)

**Top Priority
Alert Notice**

FDA Bhawan, Kotla Road,
New Delhi

Dated:

18 DEC 2014


Office Memorandum

Sub: Sub-standard quality of DPT Vaccine IP (Abhay-TAG) Batch No. TAG 05A/14 (CDL No. 4518/14) with Mfd. Dt 01/14 and Exp. Dt. 12/15, manufactured by Human Biologicals Institute, Hyderabad - regarding.

Ref: Letter No. CDL/2014/7110 dated 29.10.14 from CDL, Kasauli Vide FTS No. 68164/2014 dated 12.11.14.

This is with reference to the DPT Vaccine IP (Abhay-TAG) Batch No. TAG 05A/14 (CDL No. 4518/14) with Mfd. Dt 01/14 and Exp. Dt. 12/15, manufactured by Human Biologicals Institute, Hyderabad and declared as sub-standard by CDL, Kasauli.

In view of above, you are directed to recall the subject batch and keep vigil over quality of next batches manufactured by the firm and inform this Directorate in case of any non-compliance reported.


(Dr. G. N. Singh)
Drugs Controller General (India)

Enclosure: A test report received from CDL.

To,

Dy. Drugs Controller (I),
CDSCO Zonal Office, CDSCO Bhawan,
Beside AP T.B. Demonstration and Training Centre,
S.R. Nagar, Hyderabad - 500 038

Copy to:

1. All Zonal/ Sub-Zonal Offices of CDSCO - with the Direction to submit the action taken report to this office
2. Quality Assurance Division, CDSCO (HQ), FDA Bhawan, New Delhi.