File No. 12-01/17-DC (Pt-07)
Directorate General of Health Services
Office of the Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 17.01.2017

NOTICE

In 32nd meeting of the Apex Committee held on 03.11.2016 under the chairmanship of Secretary, Ministry of Health & Family Welfare for supervising clinical trials on new chemical entities, it was decided that-

"In future, cases of waivers need not be brought to Technical Committee and Apex Committee and these should be considered and disposed of by the Central Licensing Authority as per provisions of Drugs and Cosmetics Act, Rules and Guidelines issued by the Government from time to time and Technical Committee will act as Appellate Committee in cases of disputes".

This is for information and necessary action.

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

To

1. All officers of CDSCO (HQ)/ Zonal /Sub-zonal/Port Offices of CDSCO
2. All Stakeholders through website of CDSCO

CC:

1. PPS to Secretary, Ministry of Health and Family Welfare
2. PPS to DGHS, Ministry of Health and Family Welfare
3. PPS to Additional Secretary (F&D), Ministry of Health and Family Welfare
4. PS to JS (R), Ministry of Health and Family Welfare