ANNEXURE 1

F.No X-11026/119/2017-BD
Directorate General of Health Services
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi-110002.
? 6 SEP 2017

To
The All State Drug Controllers,

Sub: Strict Regulatory control over Manufacture, sale and distribution of oxytocin and to curb its misuse-regarding.

This office has received the letter from Ministry of Health and Family Welfare vide F.No BD/VET/CELL/13.2014(Pt-1) Dated 09-05-2017 that the following measures are to be taken inorder to comply the directions of the Hon'ble High court, Himachal Pradesh on the subject cited above

i. Constitution of a special task Force in each District of each State to ensure that no Prohibited / regulated drug including Oxytocin is freely available in each District in open market, save and accept in the manner prescribed.

ii. Concerned State Drug Controllers of the Sates where Licenses for manufacturing of Oxytocin have been issued shall examine the Licenses of all existing manufacturers of Oxytocin to ensure that the same have been issued strictly in accordance with Drugs and Cosmetics Act, 1940 and Rules 1945 and that the manufactures mandatorily comply with all the conditions of Drugs and Cosmetics Act, 1940 and Rules 1945, frame there under. Immediate appropriate actions as per the statutory provisions may be taken wherever violations of the rules are found.

iii. The State Drug Controller shall place on their respective websites by 10th of each month details of licenses issued to various manufacturers along with monthly statement of production and sales of Oxytocin with complete particulars and details made by the manufacturers. The manufacturers of Oxytocin shall in turn submit these details in advance so as to reach the office of Drug Controller by 7th of every month.

iv. The wholesalers and retailers of all prohibited scheduled drugs including Oxytocin shall maintain records, as required under the law and the same

In case, a manufacturer fails to comply with the regulatory requirements even after giving opportunity as above, the manufacturer should be directed to stop the manufacture, sale and distribution of oxytocin bulk/injection with immediate effect.

The progress in the above cases may please be intimated to the undersigned on monthly basis so as to ensure that the drug is manufactured in the country for human and animals in compliance to the regulatory provisions of the Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder and its misuse is curbed.

This may be treated on priority.

Yours faithfully,

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

Copy to: JS (R), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi.