GOVERNMENT OF NCT OF DELHI DRUGS CONTROL DEPARTMENT F-17, KARKARDOOMA, DELHI – 110 032

No. F.13(15)/Misc./HQ/2017/ 1036 to 1945

Dated: /8/9//8

To

- 1. All Drug Manufacturers in Delhi
- 2. All Chemist Associations in Delhi

Subject: Prohibition of 328 Fixed Dose Combinations by the Central Government vide Gazette Notification Nos. S.O.4379(E) to S.O. 4706 (E) – Regarding

Sir,

The Central Government in exercise of powers conferred under section 26-A of the Drugs and Cosmetics Act, 1940 has prohibited the manufacture/sale/or distribution of the 328 Fixed Dose Combinations (FDCs) for manufacture, sale or distribution with **immediate effect** (copy enclosed). This prohibition has been imposed pursuant upon recommendations furnished by the Drugs Technical Advisory Board (DTAB) for the reason that these FDCs have no therapeutic justification claimed or purported to be claimed from them. The individual notifications referred to above have been uploaded on the Department's official <u>website:</u> <u>drugscontrol.delhigovt.nic.in</u> and can also be downloaded from there.

All the stakeholders are hereby informed to stop manufacture for sale/sale or distribution of the above FDCs in the public interest with immediate effect. The unconsumed stocks of the above FDCs should be returned back through the supply chain for its scientific disposal at the source of origin. However, the stakeholders will also observe the court directions issued in this regard from time to time.

Further, the permissions granted in favour of Delhi based Pharma manufacturing units with respect to any of the above FDCs by the Licensing Authority shall stand WITHDRAWN/CANCELLED with immediate effect.

Yours faithfully,

(Atul Kumar Nasa) Head of Office/

Controlling & Licensing Authority

Encl: as above

Dated: /8/9//8

Copy for information to:

- 1. Secretary (H&FW), Government of NCT of Delhi, 'A' Wing, 9th floor, Delhi Secretariat, I.P. Estate New Delhi - 110 002.
- 2. Drugs Controller General (India), Directorate General of Health Services, FDA Bhawan, Kotla Road, New Delhi - 110 002.
- 3. Director General of Health Services, Government of NCT of Delhi, F-17, Karkardooma, Delhi – 110 032 for information &necessary action.
- 4. The President, Delhi Medical Association, DMA House, Medical Association Road, Darya Ganj, Delhi - 110 002 with a request to circulate among all their Members for information.
- 5. All DDCs/ADCs/LAs/DIs for information & necessary action.
- 6. The President, RDCA, H-28, Lajpat Nagar-II, New Delhi 110 024 for information & with request to circulate among all their Zonal Representatives and Members for compliance.
- 7. The President, Delhi Drugs Traders Association, 1501-2, 3rd Floor, Ram Gali, Bhagirath Place, Delhi - 110 006 for information & with request to circulate among all their Members for compliance.

8. All the Licensed Drugs Manufacturers located in the Government of NCT of Delhi.

(Atul Kumar Nasa) **Head of Office/**

Controlling & Licensing Authority