F. No. 4-01/2013-DC (Misc13-PSC)
Directorate of General of Health Services
Central Drugs Standard Control Organization
(FDC DIVISION)

FDA Bhawan,

Kotla Road, New Delhi

Dated: 01 JUL 2013

NOTICE

Subject: - Approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)-regarding.

The issue related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term 'new drug' in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India) had been raised in many forums from time to time. The Parliamentary Standing Committee of the Ministry of Health and Family Welfare in its 59th report on the functioning of CDSCO have also observed that the some of the State Licensing Authorities have issued manufacturing licenses for a very large number of FDCs without prior clearance from CDSCO. This has resulted in the availability of many FDCs in the market which have not been tested for efficacy and safety. This can put patients at risk.

It may be mentioned that Rule 122A, 122B, 122D, 122E and Schedule Y prescribing the requirements and guidelines for import, manufacture of New drugs including FDCs was introduced in the Drugs and Cosmetics Rules 1945 vide GSR No. 944E dated 21.9.1988. Requirements with respect to the approval of various categories of FDCs are specified in the Appendix VI of Schedule Y.

Earlier, in 2007, direction was issued to the State Drugs Controllers to withdraw 294 FDCs which were licensed without approval of DCG (I). However, the manufacturers Association got stay order from the Madras High Court. The matter is still sub-judice. Action in respect of the aforesaid 294 FDCs will be taken after the outcome of the court case in Madras High Court.

In respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authorities before 1.10.12, without the permission of DCG(I), as decided this office vide letter no. 4-01/2013-DC (Misc13-PSC) dated 15.1.2013 had requested all state/UT Drug Controllers to ask the concerned manufacturers in their State to prove the safety and efficacy of such FDCs as mentioned above before the office of DCG (I) within a period of 18 months, failing which such FDCs would be considered for being prohibited for manufacture and marketing in the country.

However so far hardly any such manufacturers have approached to CDSCO to prove the safety and efficacy of such FDCs.

In view of above, it is brought to the notice of all concerned that applications for such FDCs should be submitted to this Directorate latest by 30th August 2013 so that these applications may be processed in a timely manner.

The following procedure should be followed for filing the application for assessing the safety and efficacy of such FDCs:-

1. The concerned manufacturer(s) shall apply in Form 44 alongwith requisite Treasury Challan and supporting documents supporting the safety and efficacy of the FDC.
2. The applications will be examined in consultation with Expert committee. If considered necessary, the applicant may be asked to present their case before the committee.
3. In case of requirement of clinical trial, protocols etc. should be submitted by the firm for approval by DCG(I).
4. In case of multiple applications for the same FDC, all such applicants will have option to conduct one such study (wherever necessary) sponsored by the firm(s), if required.