

DCGI/MISC/2014 (44)  
Central Drugs Standard Control Organization  
Office of Drugs Controller General India  
FDA Bhawan, Kotla Road, New Delhi


Dated: 28<sup>th</sup> March, 2014

**OFFICE MEMORANDUM**

In light of various representations received from OPPI, FICCI, CII, IDMA and other stakeholders on relabeling issue of imported drugs, a special meeting with the stakeholders was held on the direction of Ministry of Health and Family Welfare on 26<sup>th</sup> March, 2014.

As Port Offices have started the meticulous implementation of labeling requirements, therefore, the importing organizations have expressed their inability to change as per Drugs & Cosmetics rule to India specific labeling in short span of time and approached DCGI to allow some time for transition from universal to India specific labeling so that supplies of drugs to the patients are not hampered.

Accordingly, it has been decided in the interest of patients safety and well being, that those drugs which are imported under universal packing and needs relabeling post import, in order to comply with Drugs & Cosmetics rules are given general permission under rule 104-A for three months in cases of drugs and six months for devices and cosmetics under Drugs & Cosmetics Act and Rules.

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

To

All Port/Zonal/Sub-Zonal Offices of CDSCO

Copy to:

PPS to Secretary (H&FW)/PPS to DGHS/PS to AS&DG/PS to Joint  
Secretary (R), Ministry of Health & Family Welfare