

**Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare**

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002

File No. 29/Misc/3/2016-DC (288)

Date: 04 MAY 2017

Office Memorandum

Sub:- Permission to affix the sticker indicating Date of Manufacture and Date of Expiry with respect to Medical Devices under the provisions of Drugs and Cosmetic Rules -- regarding.

This has reference to the matter regarding the interpretation of the shelf life of the Medical Devices. As per the international labeling norms the expiry date is given in the same month as that of manufacturing month and the same is not in accordance with labeling requirements of Drugs and Cosmetic Rules 1945.

In this connection, this office had given a relaxation clause wherein the importers were allowed to affix the sticker indicating the manufacturing date and expiry date as per the provisions laid down under Drugs and Cosmetic Rules 1945 till 25.05.2017(letter annexed).

This office has received some representation from firm requesting for extension of the time period as it is difficult for them to accommodate the change in the labels in the given 06 months time frame (effective from 25.11.2016)

The representation as submitted has been examined and also in view of the fact that current regulatory rules which would be effective from 01.01.2018, it has been decided by the competent authority that the provision for affixing sticker on the label indicating Date of Manufacture and Date of Expiry with respect to Medical Devices under the provisions of Drugs and Cosmetic Rules has been extended from 25.05.2017 to 31.12.2017.


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

To

1. All Port Offices of CDSCO