F. No. X-11026/247/2019-BD
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 29/11/2020

Office Memorandum

This is with reference to the requests received for the grant of permission for carrying out overprinting/stickering/stamping of imported drugs in certain cases under the provisions of Rule 104A of the Drugs and Cosmetics Rules, 1945 by the CDSCO.

In this regards, presently applications are made separately for each drug for the grant of permission under the provisions of the aforesaid Rules for making alterations for various purposes.

The matter has been examined in detail and to further simplify the procedure and to reduce the transaction time, it has been decided without prejudice to legal provisions that for drugs imported into the country, the importer can seek a comprehensive permission for all such products imported by him for overprinting/stickering/stamping as per Rule 104A of the Drugs and Cosmetics Rules, 1945 instead of seeking permission each time for the purpose of -

a) For Hospital/Institution/Government Supply – Not to be Sold
b) For Physician's sample – Not to be Sold
c) For Manage Access Program/Clinical Trial Use Only/For Post Trial Access only Not to be Sold

Provided such labeling activity shall be carried out at the licensed manufacturing premises without concealing the original label, subject to satisfaction of concerned SLA.

(Dr. V. G. Somani)
Drugs Controller General (India)

To -
1. All concerned Pharma Associations

Copy to -
1. PS to JS(R), MoHFW
2. Guard File
3. CDSCO Website