File No.:r-DNA-15011(11)/26/2025-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi 11000

Dated: 26 MAY 2025

Office Memorandum

Subject: Clarification of comprehensive permission for products imported for overprinting / stickering / stamping as per Rule 104A of the Drugs and Cosmetics Rules, 1945-Regarding

In continuation to earlier OM issued by this office vide ref.F.No.X-11026/247/2019-BD dated 29.1.2020 the following clarifications are provided for conducting labeling / over printing / stickering of products under Rule 104A of the Drugs Rules,1945 :

- The activity of labeling / over printing / stickering etc as per OM dated 29.01.2020 under Rule 104A of the Drugs Rules, 1945 is to allow strictly only for import of drugs.
- All such activities to be carried out by the importer under a valid manufacturing license in their name.
- The Licensee shall have adequate facility for storage, ancillary areas, Labeling facility etc. and will appoint at least one manufacturing and QA personnel to the satisfaction of the SLA. The QC Laboratory and personnel may be not be required for such labeling activities.
- The labeling shall comply with the current provisions of Drugs and Cosmetic Rules. The said activity will not conceal the original label. The License number and the activity carried out for this purpose should also be mentioned beside alterations made as per Rules 104A.

EXAMPLE: if the drug is for CGHS supply and that is to be written on the label, then the additional information to be added on the label as "CGHS Supply" "Overprinting done under Lic. No. MH/….A".

This is for information and further necessary action.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To:

All stakeholders through CDSCO website

Copy to:

JS (R) Min. of Health and Family Welfare, Nirman Bhawan, New Delhi.