## File No. 4-01/2023-DC (Misc. 3) Government of India Directorate General of Health Services Central Drugs Standard Control Organization (FDC Division)

FDA Bhawan, Kotla Road New Delhi-110002 Date:

To,

All State/ UT's Drugs Controllers

1 0 SEP 2025

Subject: Manufacturing and marketing of unapproved FDC's -regarding.

Sir/ Madam,

Please refer to the letter issued by this office vide File No. 4-01/2023-DC (Misc. 3) dated 11.04.2025 on the subject cited above.

In this regard, it may be mentioned that one of the FDCs namely Voglibose 0.2 mg and Metformin Hcl (as SR form) 500mg (at S.No. 31) has been found to be approved by CDSCO and the same was also recorded by Hon'ble High court, Delhi during the hearing on 14.07.2025.

Accordingly, the FDC i.e Voglibose 0.2 mg and Metformin Hcl (as SR form) 500mg (at S.No. 31) stands excluded from the list of unapproved FDCs in letter dated 11.04.2025.

Yours Faithfully,

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

## Copy forwarded to:-

- 1. All Zonal/Sub Zonal Offices of CDSCO
- 2. US (D), Ministry of Health and Family Welfare, NirmanBhawan, New Delhi.
- 3. Website of CDSCO