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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

+ **W.P.(C) 5873/2025 & CM APPL. 26834/2025**

PINNACLE LIFE SCIENCE PVT. LTD. & ORS.Petitioner

Through: **Mr.Aman Saroha with Ms.Khushi
Sharma, Advs.**

versus

UNION OF INDIA & ANR.Respondent

Through: **Mr.Abhishek Gupta, CGSC with
Mr.Kumar Kartikeya, Mr.Chanakya
Kene, Mr.Dhananjay Singh, Advs.**

**CORAM:
HON'BLE THE CHIEF JUSTICE
HON'BLE MR. JUSTICE ANISH DAYAL**

**ORDER
16.04.2026**

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1. Heard the learned counsel for the parties.
2. Proceedings of this petition filed under Article 226 of the Constitution of India lays challenge to a letter/circular dated 11.04.2025 issued by the Drug Controller General of India, Central Drugs Standard Control Organization, Directorate General of Health Services, Government of India, whereby all State/UT Drugs Controllers have been requested to ensure that the manufacturing, sale and distribution of FDCs in annexure and any other unapproved FDCs shall not be allowed in the country. The letter/circular also requests the respective Drugs Controllers to conduct an investigation



and take necessary action as per the provisions of NDCT Rules 2019 made under the Drugs and Cosmetics Act, 1940. The letter/circular also states that action so taken shall be intimated to the Office of the Drug Controller General of India.

3. In the counter affidavit filed on behalf of the respondents, it has been stated inter alia that the circular/letter dated 11.04.2025 does not relate to banning or prohibition of any drug as is the case sought to be put forth by the petitioner. Further averment made therein is that the said circular does not have the effect of banning or prohibiting the unapproved FDCs; rather it has been issued with the purpose of sensitizing all the State/UT Drugs Controllers about the menace of unapproved FDCs.

4. Paragraph 4 of the counter affidavit filed on behalf of the respondents is extracted herein below:-

“4. It is submitted at the outset that the impugned notice dated 11.04.2025 issued by the Central Drugs Standard Control Organization (FDC Division) (hereinafter referred as ‘CDSCO’) does not relate to banning/prohibition of the drugs, as alleged by the Petitioner. The said notice does not have the effect of banning or prohibiting the unapproved FDCs. Rather, it is issued with a salient purpose of sensitizing all the State/UT Drugs Controllers about the menace of unapproved FDCs which are not evaluated for their safety and efficacy and that had come to the notice of CDSCO. Notably, the manufacturing licenses of these FDCs had been subsequently cancelled by Drug Licensing Authorities (DLAs) or voluntarily surrendered by manufacturers following issuance of show case notices. The said notice notably records that:

“The approval of such unapproved FDC’s compromises patient safety and may lead to adverse drug reactions, drug interactions, and other health hazards due to the absence of scientific validation.””



5. In view of the aforesaid, we do not find any reason to continue with the proceedings of this writ petition, which is, accordingly, stands disposed of along with pending application.

DEVENDRA KUMAR UPADHYAYA, CJ

ANISH DAYAL, J

APRIL 16, 2026

S.Rawat