F. No. SND-16011(11)/10/2026-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Subsequent New Drugs Division)

FDA Bhawan, New Del
Dated: 18 MAR 2026

To,

All State/UT Drugs Controllers.

Sub: Manufacturing and marketing of unapproved drug productSodium Hyaluronate Eye Drops 0.3 % w/v -Reg.

Sir,

It has been brought to notice of this Directorate that some manufacturers are involved in manufacturing/marketing of subject cited drug product which is not yet approved by this office for manufacturing/marketing in the country and falls under the category of "New Drug".

No new drug shall be manufactured for sale unless it is approved by the Licensing Authority as defined in Rule 3 of New Drugs and Clinical Trial Rules, 2019. Further, as per Rule 80 of New Drugs & Clinical Trials Rules 2019, a person who intends to manufacture new drug in the form of API or Pharmaceutical formulation, as the case may be for sale or distribution, shall make an application for grant of permission to the Central Licensing Authority in Form CT-21 along with a fee as specified in Sixth Schedule.

In view of the above, you are hereby directed to convey the matter to all the manufacturer under your jurisdiction and cancel the product permission granted by you of subject drug.

The necessary information about the status and action taken in the matter may please be intimated to this Directorate at the earliest.

Yours Sincerely,

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

Copy of information and necessary action to:-

1. All Zonal/Sub Zonal Offices of CDSCO
2. Indian Drug/Pharmaceuticals Association Forum
3. Website of CDSCO