

**File No. SND/MA/22/000301**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organization**  
**(Subsequent New Drugs Division)**

FDA Bhawan, Kotla Road  
New Delhi - 110002 (India)  
Date-

**Order**

6 SEP 2024

Whereas, this Directorate had issued permission dated 20.08.2024 to you for manufacture and marketing of Pilocarpine Hydrochloride Ophthalmic Solution USP 1.25% w/v for the treatment of Presbyopia in adults.

And, whereas this Directorate had issued notice Dt. 04.09.2024 regarding various claims of Pilocarpine Hydrochloride Ophthalmic Solution USP 1.25% w/v made by you in various news articles (Notice enclosed).

And, whereas you have submitted response dated 05.09.2024 which has been examined and the details are as below:

- In response to the claim "first eye drop in India designed to reduce the need for reading glasses", you have stated that there are currently no other eye drops approved for the treatment of Presbyopia in India.

In this regard, you are informed that the Pilocarpine Hydrochloride Ophthalmic Solution USP 1.25% w/v has not been approved for any such claim that it is designed to reduce the need for reading glasses.

- In response to the claim "this eye drop offers a non-invasive option that can enhance near vision without the need for reading glasses" you have submitted that in the clinical trial conducted, subjects did not wear glasses to participate etc.

In this regard, you are informed that the Pilocarpine Hydrochloride Ophthalmic Solution USP 1.25% w/v is approved for the treatment of Presbyopia in adults and is not approved for such claim that these eye drop can enhance near vision without the need for reading glasses.

- In response to the claim "PresVu can provide an advanced alternative that augments near vision within 15 minutes", you have submitted that one doctor has evaluated the drug product as compared to reading glasses.

In this regard, you are informed that the Pilocarpine Hydrochloride Ophthalmic Solution USP 1.25% w/v is approved for the treatment of Presbyopia in adults and is not approved for such claim that PresVu can provide an advanced alternative that augments near vision within 15 minutes.

After a perusal of your reply, it is clear that you had failed to respond to the queries as put to you. You had tried to justify the claims for the product for which no approval

was granted. And also, whereas it is clear that you have not obtained any prior approval from the Central Licencing Authority to make such claims for the said drug product as mentioned above. Thus, you have violated the Condition No. (vi) of the permission No. MF/SND/24/000092 dated 20.08.2024 issued to you for manufacture and marketing of Pilocarpine Hydrochloride Ophthalmic Solution USP 1.25% w/v under the provisions of the New Drugs and Clinical Trials Rules, 2019. Also considering the various media reports, there is a likelihood of the general public being misled by the claims made by you, for which no approval was granted.

In view of above and considering the public interest, the permission No. MF/SND/24/000092 dated 20.08.2024 issued to manufacture and market of Pilocarpine Hydrochloride Ophthalmic Solution USP 1.25% w/v vide is hereby suspended till further order under the provisions of Rule 84 of the New Drugs and Clinical Trials Rules, 2019 of the Drugs and Cosmetics Act, 1940.

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

To,  
M/s Entod Pharmaceuticals Ltd.,  
Ashirwad Building, Opp. Badi Masjid, S.V road, Bandra (W), Maharashtra (India) –  
400050, Email: [regulatory@entodpharma.com](mailto:regulatory@entodpharma.com)

**Copy To,**

1. The Commissioner, FDA Maharashtra, 341, Bandra Kurla Complex, Opp. RBI Building, Bandra (East), Mumbai-400051.
2. The Commissioner, Food and Drug Control Administration, 1<sup>st</sup> Floor, Block-8, Dr. Jivraj Mehta Bhavan, Gandhi Nagar-382010, Gujarat.
3. DDC (I), CDSCO Zonal Office, West Zone, Maharashtra.
4. DDC (I), Ahmedabad Zonal Office, Ahmedabad, Gujarat-380015.