

F.No.12-01/12-DC Pt- 127
Directorate General of Health Services
(Office of DCG(I))

Webster

FDA Bhawan
Kotla Road, New Delhi

Dated: 10 JAN 2013

[Signature]
28/1/13

To

1. All State Drug Controllers

Sub: Cancellation of permission / license in case an applicant / manufacturer who fails to launch their product for marketing in the country within a period of six months from obtaining the permission / license from CDSCO - regarding.

Sir,

Under the Drugs and Cosmetics Rules, 1945 permission to manufacture a new drug is granted by CDSCO. Based on the permission received from CDSCO, manufacturer obtains manufacturing licence from the concerned State Licensing Authorities.

As per Schedule Y, Periodic Safety Update Reports (PSURs) of new drugs are required to be submitted every six months for the first two years after approval of the drug is granted. For subsequent two years – the PSURs need to be submitted annually. PSURs are important for assessing the safety and efficacy in post marketing scenario. However, it has been observed many times that the manufacturers do not launch the product even after years of getting approval from this office and the manufacturers do not submit the required PSUR, while the drug does not remain a new drug after a period of four years. Therefore, the assessment of safety and efficacy of such new drug in post marketing scenario remains incomplete.

It has, therefore, been decided in public interest that in case an applicant / manufacturer fails to launch the product for marketing in the country within a period of six months from obtaining the permission / license from CDSCO, the permission / license will be treated as cancelled. You are, therefore, requested to instruct manufacturers that in case the applicants / manufacturers fail to launch their products within six months after getting approval from CDSCO, the permission / license obtained from this office will be treated as cancelled.

[Signature]
(Dr. G.N.Singh)
Drugs Controller General (India)

Copy to :

1. US(D), Ministry of Health and Family Welfare, Nirman Bhawan, N.Delhi
2. PS to DGHS, Ministry of Health and Family Welfare, Nirman Bhawan, N.Delhi
3. Zonal / Sub-Zonal offices of CDSCO.

*V.H.-
15-11-2012
ADT (Dy. Secy)*

*Manish
Pl. forward
letter to all
under in.*

