अति-तत्काल / स्पीड पोस्ट द्वारा
MOST IMMEDIATE / BY SPEED POST

सं.एक्स.11011/1/2011-डीएफक्यूसी/2
No.X.11011/1/2011-DFQC
भारत सरकार / Government of India
स्वास्थ्य व परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare
स्वास्थ्य व परिवार कल्याण विभाग - Department of Health & Family Welfare

निर्माण भवन, नई दिल्ली
Nirman Bhavan, New Delhi
दिनांक 1 अक्टूबर, 2012
dated the 1 October, 2012

To

Principal / Health Secretaries of
all States/Union Territories

Subject: Directions under section 33 (P) of Drugs and Cosmetics Act 1940 for grant / renewal of manufacturing licenses of drug formulations in proper/generic name only – reg.

Sir,

The Regulatory Control over the manufacture and sale of drugs is exercised by the State Licensing Authorities appointed by the State Governments under the provisions of the Drugs and Cosmetics Act, 1940. It has been observed that at the time of the grant of the license for manufacture of a drug formulation, the trade name as submitted by the manufacturer is also endorsed by the licensing authority alongwith proper name of the product thereby giving legitimacy to market the drug under the brand or the trade name. Under the provisions of the Drugs & Cosmetics Rules, 1945, applications in various forms for grant/ renewal of a license to manufacture for sale or distribution of various categories of drugs as well as various forms for grant / renewal of such licenses require the name of the drug to be specified. Such forms for application as well as grant / renewal of the licenses do not require mentioning of any Trade Name / Brand Name

2. In view of the above, the grant of drugs manufacturing licenses under a trade or brand name is not in accordance to the spirit of the legislation. Therefore, manufacturing license for the drug formulation should be granted in proper / generic name only. In case of drug formulation containing multiple ingredients, the licence should be granted under the name of categories of product viz. "Multivitamin Tablets/Capsule/Syrup", "antioxidants, multivitamins & multi minerals tablets/ capsule/syrup' etc. However, the composition of such product shall mention the name of active ingredients as well as its strength. The

issue was also discussed in the Drugs Consultative Committee in the meeting held on 20th July, 2012.

3. In view of the above, in pursuance of the provisions contained in Section 33 (P) of the Drugs and Cosmetics Act, 1940, as amended from time to time, the Central Government hereby directs all States / Union Territory Governments to instruct their respective drug licensing authorities to grant / renew licenses to manufacture for sale or for distribution of drugs in proper / generic names only

Yours faithfully

(संजय प्रसाद)
(Sanjay Prasad)
निदेशक / Director
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Copy to: Drugs Controller General (India), FDA Bhavan, Kotla Road, New Delhi.