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MOST IMMEDIATE /BY SPEED POST

सं.एक्स.11011/1/2011-डीएफक्यूसी
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

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निर्माण भवन, नई दिल्ली
Nirman Bhavan, New Delhi
दिनांक 9 नवम्बर, 2012
dated the 9th November, 2012

To

(i) Principal / Health Secretaries of
all States/Union Territories

(ii) Drugs Controllers 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,

I am directed to refer to this Ministry's letter of even number dated 1.10.2012 conveying the directions of the Central Government in pursuance of the provisions contained in Section 33 (P) of the Drugs and Cosmetics Act, 1940 for grant / renew licenses by the State / UT drug licensing authorities for manufacture for sale or for distribution of drugs in proper / generic names only and to say that clarifications have been sought on various points in connection with the implementation of this statutory direction. Accordingly, the following clarifications are provided by the Central Government:

(i) This direction has prospective effect only.

(ii) This direction has been issued under the Drugs & Cosmetics Act, 1940.

(iii) This direction is applicable only for the manufacturing license issued by the drug licensing authorities under the provisions of the Drugs & Cosmetics Act, 1940.

(iv) This direction does not apply to the various types of certificates, namely, COPP, GMP Certificate, Free Sale Certificate, etc required for the purpose of export of drugs, as these are not issued under the Drugs & Cosmetics Act, 1940. The exports have to comply with the regulatory requirements of the importing countries which require such certificates.

(v) This direction is not applicable to grant / renewal of license for import of drugs.

(vi) This direction is not applicable to grant / renewal of license for manufacture and import of medical devices.

(vii) This Direction is independent of the draft notification GSR 748(E) dated 5.10.2012 issued seeking comments of stakeholders on amending Drugs & Cosmetics Rules, 1945 allowing issuance of licenses of single ingredient drugs in generic / proper names only.

Yours faithfully

(तरसेम चंद)
(Tarsem Chand)
निदेशक / Director
टेलीफैक्स/Telefax: 23062352

Copy to: Drugs Controller General (India), FDA Bhavan, Kotla Road, New Delhi for wide circulation.