F. No: 7-5/2017/DCG(I)/MISC(099)
Directorate General of Health Services
Office of Drug Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated:- 24 NOV 2017

To,
All State/UT Drugs Controllers

Subject: Amendment in the Drugs and Cosmetics Rules, 1945 vide Notification No. G.S.R 1337(E) dated 27.10.2017 regarding validity of licence & provision for joint inspection of manufacturing premises for grant of licence for manufacture for sale of Drugs and Cosmetics & verification of compliance –Reg.

Sir,

Ministry of Health and Family Welfare, Government of India has amended the Drugs and Cosmetics Rules, 1945 vide Notification No. G.S.R.1337 (E) dated 27.10.2017 providing that manufacturing licence for drugs and cosmetics and approval of drugs/cosmetics testing laboratories shall remain valid if the licencee deposits licence retention fee before the expiry of period of every succeeding five years from the date of issue, unless, it is suspended or cancelled by the licensing authority.

The amendment also provides that before grant of licence in Form 25 or Form 25A or Form 25B or Form 25F or Form 28 or Form 28A or Form 28B or Form 28D or Form 28DA to manufacture for sale or for distribution of Drugs or in Form 32 or Form 32A or Form 33 for manufacture of Cosmetics, the State Licensing Authority shall cause the manufacturing premises to be inspected jointly by the Central and State Drugs Inspectors. Further, the premises licensed shall be inspected jointly to verify the compliance with the conditions of licence and the provisions of the Act and the Rules not less than once in three years or as needed as per risk based approach.

Copy of the notification is enclosed herewith for your information and necessary action.

In this regard, for effective and uniform implementation of the provisions of joint inspection of manufacturing premises, detailed guidelines would be prepared in consultation with the State Drugs Controllers and other stakeholders.

However, in the meantime to ensure smooth processing of applications for grant of manufacturing licenses following modalities may be followed.

i. Applications for the grant of manufacturing licenses complete in all respect as per the provisions of the Drugs and Cosmetics Act, 1940 an Rules, 1945 should be submitted by the manufacturers to the respective State Licensing Authority.
ii. The State Licensing Authority should fix a date for joint inspection of the manufacturing premises, in coordination with the respective Zonal/Sub-Zonal offices of CDSCO at least seven days prior to the date of inspection.

iii. In case drugs inspector of CDSCO Zonal/Sub-Zonal offices is not available on any specific date, drugs inspector from CDSCO (HQ) will be deputed for the joint inspection.

iv. Proper coordination between the State Licensing Authorities, CDSCO HQ and Zonal/Sub-Zonal offices should be ensured for timely inspection and processing of the applications.

v. In case of deficiency in the application in respect of any inspection, the joint inspection team may verify such documents during the inspection and record details of the same in the inspection report.

Your cooperation and valuable feedback or suggestions in this regard will be highly appreciated for further improvement in the implementation of the new rules.

Yours faithfully

24-11-17

Dr. G. N. Singh
Drugs Controller General (India)

Copy to : ACC Zonal/Sub-Zonal Offices, CD

c.c. PPS to DGHS

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