

Handwritten notes and signatures in blue ink, including initials and dates like 12/12 and 19/12.



COMMISSIONERATE
Food & Drugs Control Admin
GUJARAT STATE
13 FEB 2014
25
IND NO.

Most Immediate
Speed Post
F. No. 7-5/2014 DCG Narcotics (MD)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi
Tel: 011-23236975
Fax: 011-23236973
E-mail: dcj@nb.nic.in
Website: www.cdsc.nic.in

Dated: 12 8 JAN 2014

DR. G. N. SINGH
DRUGS CONTROLLER GENERAL (INDIA)

Dear

The Narcotics Commissioner, Central Bureau of Narcotics (CBN), Gwalior, had written a letter to all the state Drugs Controllers vide letter no. 08/01/Narco/2012-11372 dated 09th August, 2012 that all manufacturers of bulk drugs/formulations of manufactured Narcotics Drugs under Narcotics Drugs and Psychotropic Substances (NDPS) Act/Rules 1985 require to obtain necessary manufacturing license from their office and requested them to add a condition to their license that they are required to approach the Narcotics Commissioner, Central Bureau of Narcotics (CBN), Gwalior, for issue of manufacturing license under rule 37 of the NDPS rules. A copy of the said letter was forwarded to your office by this office vide letter number 7-5/2012 DCG Misc (CBN) dated 01st October, 2012. However copy of the letter is again enclosed for your ready reference.

As you are aware that a license to manufacture bulk drugs/ formulations is granted by your office under the Drugs and Cosmetics Act. However for the manufacture of drugs listed as "manufactured drugs" as per Section 2(xi) of the NDPS Act 1985, a license is also required to be obtained from Narcotics Commissioner, Central Bureau of Narcotics (CBN), Gwalior, as per rule 37 of the NDPS Rules. However as per Rule 39 of the NDPS rules the license cannot be granted unless the applicant produces the license granted by your office.

CBN has now brought to the notice of this office that a pharmaceutical company has been found to be manufacturing a narcotic drug without obtaining requisite license and obtaining quota from CBN, Gwalior. This is considered as a serious offence under the NDPS Act and rules.

In view of the above, you are requested to again direct all the manufacturers located in your State manufacturing the "manufactured drug" defined under NDPS Act/Rules to comply with the provisions of the NDPS Act/Rules and ensure that the

manufacture of the said drugs is in the manner prescribed as under the CBN website cbn.nic.in. Action taken in the matter may kindly be communicated to this office.

This may be kindly accorded 'Top Priority'.

Your's Faithfully,


(Dr. G. N. Singh)

To

**The Commissioner,
Food and Drugs Control Administration
1st Floor, Block No.-8,
Dr. Jivraj Mehta Bhawan
Gandhi Nagar-382010 (GUJARAT)**

Copy to:

Director (Drugs),
Ministry of Health and Family Welfare,
Nirman Bhawan, New Delhi