No. 7-5/2018/Misc./034 (NOC)
Government of India
Director General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 02 AUG 2018

To,
All States/UT Drugs Controllers

Subject: NOCs for Manufacture of Unapproved/Banned/New Drugs Solely for Export Purpose-Reg.

NOCs for manufacture of unapproved/banned/new drugs solely for export purpose are granted as per the Guidance Document issued by CDSCO.

The above activity was delegated to CDSCO Zonal offices vide File No. DCG (I)/Misc/2011 dated01 June 2011 with effect from 20 June 2011.

In order to streamline the process and facilitate the ease of doing business, it has been decided with the approval of the Ministry of Health & Family Welfare, Government of India that the process of grant of such NOCs by the CDSCO shall be discontinued and such NOCs shall be granted by the State Licensing Authorities themselves after satisfying that the following conditions are complied with in the process of grant of permission for manufacture of unapproved/banned/new drugs:

1. The applicant shall provide copy of valid export order.
2. The applicant shall provide copy of manufacturing licence issued under Drugs & Cosmetics Act, 1940 and Rules, 1945.
3. The applicant should mention whether the batch to be exported has undergone Quality control testing or shall be tested at the destined site.
4. The applicant shall ensure that the drug(s) manufactured on the basis of the permission granted is exported and that no part of it is diverted for domestic sale in India through a declaration in the form of an affidavit on non-judicial paper.
5. The applicant shall maintain a stock register for quantities of API purchased for manufacturing drug formulations manufactured, consignments exported and remaining stocks of drugs and bulk drugs which will be open for a periodic inspection by the State Licensing Authority.
6. The applicant shall make available for inspection of the appropriate authorities, on completion of the export orders, information regarding

each consignment dispatched, remaining stock of drug and related raw materials and intermediates in hand.

7. The applicant shall ensure physical destruction of all un-exported quantity of drugs. This should be included as a condition of manufacturing license issued to the applicant by the State licensing authority.

8. In the event of cancellation of the export order, the manufacturer shall ensure the physical destruction of all unexported quantity of the drug and shall submit a declaration to State Licensing Authorities in the form of affidavit on non-judicial stamp paper.

9. The applicant shall ensure that the drug for which permission has been given shall cease to be manufactured or exported if the drug is prohibited in future in the country or in the importing country.

10. In the case of drugs covered under the Narcotic Drugs and Psychotropic Substances Act, 1985 (NDPS), the applicant shall obtain NOC from the Narcotic Commissioner of India, Central Bureau of Narcotics, Gwalior. The batches to be exported shall undergo quality control testing under the control of CBN Gwalior or at destination site.

Accordingly, you are requested to take necessary steps in this regard so that with effect from 20th August, 2018, such NOCs for manufacture of unapproved/banned/new drugs solely for export purpose are issued by your office.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Copy to:

1. All Zonal/Sub Zonal/Port offices of CDSCO
2. IPA/IDMA/OPPI/BDMA/FOPE/CIPI

Copy for information:

PS to JS (R)