File No: Import/Misc/129/2019-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Import and Registration Division)

FDA Bhawan, Kotla Road,
New Delhi
Date: 18/10/2019

Office Memorandum

Subject: Monitoring the end use of drugs which are meant for dual use- Regarding.

This is in reference to the OM of even no dated 05th July 2019 issued by this office wherein a list of dual use APIs was enclosed and all zonal/ Sub zonal/Port offices of CDSCO were requested to strictly monitor the end use of dual use Active Pharmaceutical Ingredients.

In this regard, this office has received representations from various stakeholders requesting for waiving of requirement of dual use NOC.

Accordingly, the matter was examined and it has been decided that if the manufacturer himself is importing such products for their end use (other than medicinal use), one time dual use NOC may be granted for one year to such manufacturers under the intimation to this office based on the assessment of at least one year data and written undertaking by the manufacturer justifying the quantity proposed for one year. The period of one year may be further relaxed if the data submitted and the operations carries out by the operators indicate to prove that it is for self consumption for further manufacturing.

However, you are requested to strictly monitor the end use of dual use Active Pharmaceutical Ingredients and action taken in this matter shall be communicated to this office.

(Dr. V. G. Somani),
Drugs Controller General (India)

To:

All Zonal, Sub-zonal and Port offices of CDSCO.

Copy to:

1. Joint Secretary (R), Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi.
2. Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Shastri Bhawan, New Delhi.