GUIDANCE FOR EXPORT NOCFOR MANUFACTURE OF UNAPPROVED / BANNED / NEW DRUGS ALONG WITH ANNEXURES

Sr. No.	PARTICULAR DETAILS
1.	Application for Export NOC on company's letterhead duly signed and stamped by the Authorized Signatory (Name & Designation) shall include following details
	a) Covering Letter
	b) Valid Manufacturing License
	c) List of products (s) to be exported
	d) Name of the drug (s)
	e) Whether the batch to be exported will undergo Quality Control Testing at Manufacturing site and/or will be tested at the destined site
	f) Dosage form (s)
	g) Composition and strength (s)
	h) Quantity
	i) Country/Countries to be exported
	j) Place(s) of manufacturing
	k) Name & address of the firm
2.	Copy of valid Purchase order/valid Export order /Performa invoice shall include following details
	a) From foreign buyer in the name of Manufacturer/in the name of trader duly signed by Competent Authority/Authorized Signatory.
	b) If in the name of trader (Letter from trader in the name of Manufacturer along valid Purchase Order No. in favor the Manufacturer by Trader) required to be submitted along with application signed by the Competent authority/Authorized Signatory of the Manufacturer
	c) Self attested and recent order not more than 6 months prior to application made by the firm
	d) Proforma Invoice/Purchase Order of importing country should include details of Unapproved Drug/approved new drug/Banned drug
	e) Should be addressed to Manufacturer mentioning the required quantity of drugs
3	Reconciliation Data for the Formulations for the quantities permitted earlier for Specific Quantity Export in the following Format . Reconciliation Data: Mfg. Lic. No.: Export NOC No. & issue date: Quantity Permitted for Export: Country permitted to Export: Name & address of the firm to which the drug was exported:

Sl. No.	Name of the drug	B. No.	M/D	E/D	Batch Size	Qty. Manufactured	Qty. Exported	Invoice No. & Date	Shipping Bill No.	Importing Country	Remaining Stock available

ANNEXURE–I

LEGAL UNDERTAKING TO BE SUBMITTED BY THE BULK DRUG MANUFACTURER OF BANNED/ UNAPPROVED DRUGS/ APPROVED NEW DRUGS FOR EXPORT PURPOSE OR FOR SALE TO MANUFACTURING UNITS MANUFACTURING FORMULATIONS ONLY FOR EXPORT

(on Rs. 100/-non-judicial stamp paper)

I/We,_____S/o _____having premises at _____aged about _____do hereby solemnly affirm and undertake as under:

1. That We_____having the manufacturing premises at_____and hold Manufacturing license no. _____in Form _____ for the manufacture of drugs.
2. That I undertake to manufacture and sell total Quantity_____of drug _____to **M/s.**_____havingthemanufacturingpremises at_____ _____for the purpose of manufacturing _____solely for export to _____.
3. That I undertake to maintain books and records of transaction of above said unapproved/ approved new drug/ banned drug for which NOC will be granted.
4. That I undertake to allow the inspection of the books and records as well as the actual usage of _____**(Name of API)** by the inspector appointed under the Drugs and Cosmetics Act as and when required.
5. That the bags/containers of the said drug along with other requirements of labeling and packaging also mention ---"for further manufacturing".
6. That the above said quantity of the unapproved/ approved new drug/ banned drug shall not be diverted for sale in India/or used for any other purpose in India other than for export purpose only.
7. In the event of non-materialization of export due to cancellation of export order etc. the same should be intimated to the concerned CDSCO & State Licensing Authorities and the manufacturer shall ensure physical destruction of such stocks in the presence of State Licensing Authority.
8. The batch to be exported shall undergo Quality Control testing as per specification of importing country and will comply with allthe requirements of importing country including quality standards

DEPONENT

VERIFICATION

Verified on this _____**day of** _____that the contents of my above undertaking are true and that no part it is false and that nothing material has been concealed herefrom.

DEPONENT

ANNEXURE–II

LEGAL UNDERTAKING TO BE SUBMITTED BY THE FORMULATION MANUFACTURER OF THE BANNED/ UNAPPROVED DRUGS/ APPROVED NEW DRUGS FOR EXPORT

(on Rs.100/-non-judicial stamp paper)

I/We_____S/o _____, Authorized Signatory <Designation> of M/s _____having premises at_____ and age about_____yrs do hereby solemnly affirm and undertake as under:

1. That I/we have received Purchase Order for supply of following Drug Formulation's for export purpose as mentioned below:

Name of Drug Formulation	Quantity in no's	PO no. and date	Overseas Buyer Name issuing PO	Export to (Name and Address of the Firm)

2. That I am the buyer of_____(Name of the drug) as an API from M/s (name of address of manufacturer) Quantity_____in Kg/mg for manufacturing of said Formulation's solely for export purpose.
3. That I/We undertake to use_____**kg/mg** (Quantity) of above said drug banned/unapproved/approved new API/Bulk Drug for the purpose of manufacturing **(name of formulation)** solely for export to_____country.
4. That I undertake the entire quantity of the drug(s) manufactured on the basis of the above NOC shall be exported and no part of it will be diverted for domestic sale in India.
5. That I undertake the stocks of the drugs manufactured solely for export shall invariably bear the inscription "For export only - Not for domestic consumption " on the labels affixed to their cartons/packaging.
6. That I undertake to submit a certificate in below mentioned format after completion of the formulation development.

S. No.	Quantity of the Formulation manufactured	API/Bulk Drug used for manufacturing of Formulation	Remaining API/Bulk Drug in hand

7. That I undertake to maintain separate stock register for quantities of API purchased for manufacturing, drug formulation manufactured, and remaining stocks of the drugs and API which will be open for a periodic inspection by the Authorities.
8. That I undertake to allow the inspection of the books and records as well as the actual usage of _____**(name of drug)** by the inspector appointed under the Drugs and Cosmetics Act as and when required.
9. In the event of cancellation of the relevant Export Order, I shall ensure the physical destruction of all unexported quantity of the drug(s)
10. The batch to be exported shall undergo Quality Control testing as per specification of Importing Country and will comply with all the requirements of importing country including quality standards.

DEPONENT

VERIFICATION

Verified on this _____day of _____that the contents of my above undertaking are true and that no part it is false and that nothing material has been concealed here from.

DEPONENT