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7-5/ 2010/ DCGI/ Misc- Export

DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANISATION
OFFICE OF DRUG CONTROLLER GENERAL (INDIA)

FDA Bhawan, Kotla Road,
ITO (near Balbhavan), New Delhi
Dated: 28 JAN 2014

Office Memorandum

Subject: Procedure for grant of NOC for manufacture ofunapproved/ approved new drug/ banned bulk drug for the purpose of export where the bulk drug is required to be obtained from another manufacturer- reg.

For manufacturer of unapproved or approved new drug or prohibited drugs for export, 'NOC' is granted by CDSCO on case-by-case basis against valid export order. The issue of manufacture of such drug for export by the manufacturer of drug formulation after obtaining the Active Pharmaceutical Ingredient (API) from other bulk drug manufacturer in our country has been examined by the office of DCG (I) in consultation along with the Ministry of Health and Family Welfare. It has been decided that along with NOC to the formulation manufacturer for export of its drug formulation, an NOC to the API manufacturer of the said bulk drug required for manufacture of formulation may also be granted to the API manufacturer for manufacturing the specific quantity of API for sole supply to the formulator.

The following procedures for granting NOC to the manufacturers of such bulk drug/API and manufacturers of formulations for export are required to be followed while processing such applications:

a) The formulation manufacturer should apply for NOC to the CDSCO Zonal office along with purchase order and quantity required;
b) The applicant will also be required to submit legal undertaking in the prescribed format from bulk API manufacturer;
c) Based on the application and the legal undertaking submitted by the applicant, an NOC would be issued in prescribed format with copies marked to State Licensing Authority, Zonal Office, DDC (I) / ADC (I), if the bulk drugs manufacturer is situated in other zones and port offices.
d) The manufacturing site / unit of formulation manufacturer will be regularly checked by Drug Inspectors / ADC (I)s to verify that API and formulation of unapproved drugs are not diverted for sale in the country.

It may kindly be seen that both the manufacturers of such API / bulk drugs and the manufactures of the formulations who would use such bulk drugs would be required to furnish legal undertakings in this regard. In the event of non-materialization of export for some reason, the same would be intimated to the State licensing Authorities concerned and the manufactures shall ensure physical destruction of such drugs in the presence of State Licensing Authorities.

The format of NOC to be granted, legal undertaking to be submitted by the manufacturer of unapproved or approved new drug or banned API and the manufacturer of drug formulation are forwarded herewith.

The above procedure is being issued with the approval of the Ministry of Health and family Welfare.

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

P.T.O

Encl:

1. The format of NOC.
2. Legal undertaking to be submitted by the manufacturer of the unapproved or approved new drug or banned drug for export.
3. Legal undertaking to be submitted by the manufacturer of the unapproved or approved new drug or banned drug for sale of API drug to formulation only for export.

To,

All DDC (I), of Zonal Office and Sub zonal of CDSCO.

Copy for information to:

1. PPS to DGHS, Directorate General of Health Services, NirmanBhawan, New Delhi.
2. PS to AS and DG (CGHS), Ministry of Health and Family Welfare, NirmanBhawan, New Delhi.
3. PS to Joint Secretary (R), Ministry of Health and Family Welfare, NirmanBhawan, New Delhi.
4. All Port Offices of CDSCO.
5. CDSCO Website.

File No.

Dte. General of Health Services

Office of Drugs Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi – 110002
Dated

To

M/s__ Formulation manufacturer__
Address

Subject: NOC for manufacture for export of unapproved/ approved new drug/ banned drug for Export to _____- Regarding.

Sir,

Ref: Your application No. _____ dated _____and export order from M/s _____under export order no___ dated _____.

No Objection Certificate (NOC) is hereby granted to you for the manufacture the following formulation for export only.

Name of Drug	Quantity	Country of Export

You are also permitted to obtain the bulk drug for the purpose of converting the same into the formulation for export only from the following manufacturer-

Name and address of the API manufacturer	Name of the API	quantity

The above NOC is subject to the following conditions to be compiled with–

A. <u>formulation manufacturer</u>:-

1. The drug for export will be manufactured by M/s _____at _<<formulation site>>__ and shall utilize API manufactured by M/s_____ at _____.

2. The batch (es) of the formulation manufactured for export shall undergo quality control testing before export.

3. You are requested to ensure that the entire quantity of the drug(s) manufactured on the basis of the above NOC is exported and no part of it is diverted for domestic sale in India. An undertaking to this effect on non-judicial stamp paper shall be submitted by you to the State Licensing Authority with a copy to the Zonal office.

4. 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.

5. You shall submit a certificate in the below mentioned format after completion of the export to the State Licensing Authority.

Sl. No	Quantity of drug manufacture	Quantity exported to <<country>>	API quantity in hand (kgs)

6. You shall maintain a separate stock register for quantities of API purchased for manufacturing, drug formulation manufactured, consignments exported and remaining stocks of the drugs and bulk drugs which will be open for a periodic inspection by the State as well as Central Drugs Control Authorities.

7. You shall submit the information pertaining to quantities of drugs manufactured, exported and stock in hand to the State Licensing, Authority and Zonal Office of CDSCO quarterly.

8. You shall ensure that in the event of non-materialization of export due to cancellation of export order etc. the same shall be intimated to the concerned State Licensing Authority and the manufacturer shall ensure physical destruction of such stocks in the presence of State Licensing Authority. (This should be included as condition in the manufacturing license issued by the State Licensing Authority).

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

10. In the event of rejection of drug by the country of import, or banning of the drug in the interim in the importing country, the material will not be allowed to imported

Yours faithfully

DDC (I), Zonal Office

1. Copy forwarded to the concerned State Licensing Authority for grant of necessary license/ permission for manufacture of formulation for export only incorporating the conditions as mentioned in the NOC for compliance.

2. Copy forwarded to the concerned DDC (I) where the manufacturer of the bulk drug is located with the request that similar NOC may be issued to the concerned bulk drug manufacturer for manufacture of API and supply to M/s _____for manufacture of formulation at _____ for export and copy forwarded to the State Licensing Authority for grant of necessary license permission to manufacture the bulk drug.

DDC (I), Zonal Office

Annexure I

Legal undertaking to be submitted to SLA/ Central Drugs Standard Control Organisation (CDSCO) Zonal office by the bulk drug manufacturer of the banned/ unapproved drugs for sale of drug to manufacturing units manufacturing formulations only for export.

I/We.....
S/o..... having premises at ..... aged about .....do hereby solemnly affirm and undertake as under:

1. That I/We M/s..... having the manufacturing premises at ..... and hold manufacturing license no ..... in form 25/28 for the manufacture of drugs.

2. That I undertake to manufacture and sell .....mgs/ kgs (Quantity) of the drug _____ to M/s ..... (Name and address of manufacturing unit) for the purpose of manufacturing ..... (Name of formulation) solely for export to the country .....

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 the drug) 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 into the country/ or used for any other purpose.

7. In the event of non-materialization of export due to cancellation of export order etc. the same should be intimated to the concerned State Licensing Authorities and the manufacturer shall ensure physical destruction of such stocks in the presence of State Licensing Authority.

DEPONENT

VERIFICATION

Verified on this .....day of..... (Month & Year) 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

Annexure II

Legal Undertaking to be submitted to state licensing authority along with a copy to Central Drugs Standard Control Organisation (CDSCO) Zonal office by the formulation manufacturer of the banned/ unapproved drugs for export.

I/We.....
S/o..... having premises at ..... aged about .....do hereby solemnly affirm and undertake as under:

1. That I am the buyer of..... (Name of the drug) as an API from M/s..... (Name and full address of the Manufacturer) Quantity ..... Kgs/mgs.

2. That I undertake to use.....mgs/kgs (Quantity) of above said banned/ unapproved drug for the purpose of manufacturing ..... (Name of formulation) quantity ..... at above licensed premises solely for export to ..... (Country name).

3. 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 be diverted for domestic sale in India.

4. 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.

5. That I undertake to submit a certificate in the below mentioned format after completion of the export.

Sl. No	Quantity of drug manufacture	Quantity exported to <<country>>	API quantity in hand (kgs)

6. That I undertake to maintain separate stock register for quantities of API purchased for manufacturing, drug formulation manufactured, consignments exported and remaining stocks of the drugs and API which will be open for a periodic inspection by the State as well as Central Drugs Control Authorities.

7. That I undertake to allow the inspection of the books and records as well as the actual usage of _____ (Name of the drug) bythe inspector appointed under the Drugs and Cosmetics Act as and when required.

DEPONENT

VERIFICATION

Verified on this .....day of..... (Month & Year) 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