F. No. 7-5/2014/DCGI/IM/057

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

FDA Bhawan, Kotala Road,
ITO (Near Balbhavan), New Delhi

Dated :- 13.02.2015

Office Memorandum

Subject: Grant of No Objection Certificate for procuring Unapproved / Approved New Drug (Bulk) for R&D / Formulation Development / manufacture of Exhibit Batches for Overseas Registration Purpose - regarding.

Procedure for grant of NOC for manufacture of drug for export by the manufacturer of drug Formulation after obtaining the Active Pharmaceutical Ingredient (API) from other Bulk Drug Manufacturer of the said bulk drug required for the manufacture of formulation for manufacturing specific quantity of API for sole supply to the formulator, was laid down in this Office Memorandum No. 7-5/2010/DCGI/Misc. Export dated 28.01.2014. However under the Drugs & Cosmetics Act 1940 and Rules made thereunder there is no prescribed procedure for manufacturer to supply Unapproved Bulk Drug/Approved New Bulk Drug for Formulation manufacturers for R&D/ Formulation Development/ Manufacture of Exhibit batches for Export purpose. Even though the technology to manufactureUnapproved BulkDrug/Approved New Bulk Drug is available with Indian manufacturer the firms involved in R&D/Formulation Development/ Manufacture of Exhibit batches for Export purpose are forced to procure them from other countries due to lack of prescribed procedure.

In order to obviate the above situation, the following revised procedure for grant of NOC to the manufacturers of Unapproved Bulk Drug/Approved New Drug (Bulk) for the purpose of supply to the formulators engaged in R&D/ Formulation Development/manufacture of Exhibit batches for export purpose, in supersession of the

guidelines laid down in this office dated 28.01.2014, is laid down for the benefit of all stake holders

1. The manufacturer of the formulation for the purpose of test and analysis shall apply for NOC to the concern zonal office of CDSCO mentioning the address and manufacturing site of the API manufacturer where the bulk drug will be manufactured and giving of the name and quantity of the API to be manufactured, justification for the Quantity and purpose for which it is intended to be used along with license in Form- 29.
2. The application shall be submitted along with undertakings in the prescribed formats from the manufacturer of the API (Annexure-I) as well as from the manufacturer of the formulation (Annexure-II).
3. Based on the application and the undertaking submitted by the applicant, an NOC will be issued in the prescribed format (Annexure - III) after consideration of the application by the Deputy Drugs Controller (I) of the concerned zone along with copies marked to State Licensing Authority, where the applicant is located and to the Zonal office under which the API manufacturer is situated and to the API manufacturer.
4. The manufacturer of the API, then in turn will obtain a license in Form- 29 for manufacture of the API for test and analysis and supply the same to the firm holding the said NOC.
5. The formulations manufactured under the NOC will be labeled with the words "Not for medicinal use, for the purpose of test and analysis only." The manufacturer shall ensure physical destruction of the formulation after accomplishing the intended purpose.
6. The manufacturing site / unit where the API is manufactured and the where formulation is subjected to test analysis shall be monitored by the State Licensing Authorities under whose jurisdiction the manufacturers are located and ensure that the product are not diverted for any other use or for sale in the country.

7. Physical destruction of all unutilized quantity of the bulk drug shall be carried out under intimation to the Licensing Authority as per conditions of the NOC / manufacturing license granted by the State Licensing Authority.
8. The formulation manufacturer shall inform the State Licensing Authority as well as zonal office of CDSCO after the completion of the test and analysis activity and the physical destruction of the quantities left unused.

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

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

To,

1. All Zonal / Subzonal officers of CDSCO
2. State / UT Drugs Controllers
3. Drug Manufactures Associations

Copy forwarded for information to:

1. PPS to Secretary, Health and Family Welfare
2. PPS to DGHS
3. PS to JS (R)
4. Guard file

Annexure I

Notarised Legal undertaking to be submitted to State Licensing Authority and Central Drugs Standard Control Organization (CDSCO) Zonal office by the bulk drug manufacturer of the unapproved / approved new drugs for the purpose of supplying to the formulators for R&D/Formulation development/manufacture of exhibit batches for overseas drug registration purpose.

I/We_____ S/o_____ of M/s_____ having premises at_____ aged about ____do hereby solemnly affirm and undertake as under:

1. That M/s_____ having manufacturing premises at _____ hold manufacturing licence in Form 25/28.

2. That I undertake to manufacture for supplying _____mg/gm/kg (quantity)of the drug _____to M/s_____ (Name and address of the formulator seeking NOC) for the purpose of manufacturing _____ (Name of formulation) solely for R&D/Formulation development / for manufacturing Exhibit batches and generation of data for overseas drug registration purpose.

3. That I undertake to maintain books and records of transaction of above said unapproved/ approved new 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, 1940 as and when required.

5. That the bags/containers of the said drug along with other requirements of labeling and packaging also mention ---"Not for Medicinal Use" and "For test or analysis only"

6. That the above said quantity of the unapproved/ approved new drug shall not be diverted or used for any otherpurpose.
7. In the event of the cancellation of the order by the formulator I shall ensure physical destruction of the stock in the presence of the 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

Notarised Legal undertaking to be submitted to State Licensing Authority along with a copy to Central Drugs Standard Control Organization (CDSCO) Zonal office by the formulation manufacturer of the unapproved / approved new drugs for R&D/Formulation development/manufacture of exhibit batches for overseas drug registration purpose.

I/We_____ S/o_____ of M/s_____ having premises at_____ aged about ____do hereby solemnly affirm and undertake as under:

1. That I intend to buy _____ (Name of the drug) as an API from M/s_____ (Name and full address of the Manufacturer) of Quantity_____kg/mg for R&D/Formulation development/manufacture of exhibit batches for overseas drug registration purpose.

2. That I undertake to use the above quantity of the bulk drug for the purpose of manufacturing _____ (Name of formulation) of quantity_____ at above licensed premises solely for the specified purpose.

3. That I undertake the entire quantity of the drug(s) manufactured on the basis of the above NOC shall be used for the specified purpose and none of it will be diverted for domestic sale in India.

4. That I undertake the stocks of the drugs manufactured shall bear on its label "Not for Medicinal Use" on their cartons/packaging.

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

Sl.No.	Quantity of the formulation manufactured	API quantity in hand (kg)

6. 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 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) by the inspector appointed under the Drugs and Cosmetics Act as and when required.

8. That I undertake to destroy the formulations manufactured after the intended purpose is accomplished.

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

To

M/s. .....(API Manufacturer)

.....(Address)

Sub: NOC for manufacture for supply of unapproved / approved New Drug (bulk) for R&D/Formulation development/manufacture of Exhibit batches for export purpose– regarding

Ref: Your application No. _____ _____ dated _____ for issue of NOC

Sir,

No Objection Certificate (NOC) is hereby granted to you for the manufacture of the following bulk drug:

Name of Drug	Quantity

for supplying to:

Name and address of the Formulation manufacturer	Quantity

exclusively for the purpose of R&D/Formulation development/manufacture of Exhibit batches for export purpose subject to the following conditions:

1. The drug will be manufactured by you at _____ (Address of Mfg. Facility).
2. The label of the container shall bear the words "Not of Medicinal Use" and "For test or analysis only" in bold letters.
3. You are required to ensure that quantity of the drug(s) manufactured on the basis of the above NOC is supplied to the formulation manufacturer for the specified purpose and no part of it is diverted for domestic sale in India through a declaration.
4. You are requested to submit the information pertaining to quantities of drugs manufactured and supplied to the State Licensing Authority and Zonal Sub zonal of CDSCO after completion of the supply under this approval.
5. In case of Narcotics/Psychotropic Drugs, you are also directed to approach The Narcotic Commissioner of India, 19th The Mall Morar, Gwalior-6 so far as the provisions of the NDPS Act, 4985 and Rules made there under.
6. It may please be noted that this NOC is not for any commercial use and is non-transferable.
7. You shall ensure that in the event of non- materialization of formulation development 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).

8. You shall ensure destruction of the formulations after the intended purpose is accomplished.

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 R&D/Formulation development/manufacture of Exhibit batches for overseas drug registration purpose only incorporating the conditions as mentioned in the NOC for compliance and monitor the API and formulation manufactured along with the quantities and records etc.

2. Cop forwarded to the concerned DDC (I) where the manufacture 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 R&D/Formulation development/manufacture of Exhibit batches for export purpose and copy forwarded to the State Licensing Authority for grant of necessary license permission to manufacture the bulk drug.

DDC(I), Zonal Office

9.