सूचना का अधिकार

सत्यमेव जयते

भारत सरकार
वाणिज्य एवं उद्योग मंत्रालय
वाणिज्य विभाग
उद्योग भवन, नई दिल्ली-110011
Government of India
Ministry of Commerce & Industry
Department of Commerce
Udyog Bhawan, New Delhi-110011
http://commerce.gov.in

No.15/73/2013-EP(Engg)

Dated the 25th March, 2014.

To

Dr. P.V. Appaji,
Director General,
Pharmexcil,
Hyderabad.

Subject : Procedure for grant of 'NOC for manufacturer of unapproved/ approved new drug/banned bulk drug/ for the purpose of export where the bulk drug is required to be obtained from another manufacturer - regarding

Sir,

I am directed to enclose a copy of O.M. No.7-5/2010/DCG(I) Misc. Export dated the 13th March, 2014 received from the Department of Health & Family Welfare on the above mentioned subject and to request that the same may please be circulated to the member exporters for their information.

In this connection, you may also clarify as to whether the new guidelines issued by DCGI meets the requirements of the Industry and whether any of the other issues raised in the meeting held on 13.9.2013 are still pending.

Yours faithfully,

(Bahadur Singh)
Section Officer

contd..

No.7-5/2010/DCG(I) Misc. Export/[FTS No.222514(R)]
Government of India
Ministry of Health & Family Welfare
(DFQC Section)

Nirman Bhavan, New Delhi
Dated the [illegible] March, 2014

OFFICE MEMORANDUM

Sub: Procedure for grant of 'NOC' for manufacturer of unapproved/ approved new drug/banned bulk drug for the purpose of export where the bulk drug is required to be obtained from another manufacturer – regarding.

The undersigned is directed to refer to the letter No.15/73/2013-EP (Pharma) dt. 23.09.2013 on the above subject and to say that the issue relating to specific 'export permission' has been examined in consultation with the DCG(I) and it has been decided that the following procedures for grant of 'NOC' for manufacturer of unapproved/approved new drug/banned bulk drug/API and manufacturers of formulations for export are 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 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.

2. Both the manufacturers of such API/bulk drugs and the manufacturers 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 manufacturers shall ensure physical destruction of such drugs in the presence of State Licensing Authorities.

3. 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 along with necessary guidelines in this regard have been circulated among all the zonal offices and sub zonal offices of the CDSCO vide DCG(I)'s OM No.7-5/2010/DCG(I)/Misc-Export dated 28th Jan., 2014. A copy of the same is enclosed for ready reference. Also, the aforesaid procedure has been uploaded on the CDSCO's web-site.

Encl: A/A.

(Sudhir Kumar)
Under Secretary to the Government of India
Telefax : 23062861

The Commerce Secretary
[Kind. Atten: Shri Rajeev Kher]
Room No.143, Udyog Bhawan,
New Delhi.

Procedure for grant of NOC for manufacture of unapprovedapproved new drugbanned bulk drug for the purpose of export where the bulk drug is equired to be obtained from anothre manufacturer.

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