IMP-12/1/2024-eoffice

Government of India
Directorate General of Health Services Central
Drugs Standard Control Organization
(Import & Registration Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 30 APR 2024

To

All States/UT Drugs Controllers

Subject: NOC's for Manufacture of Unapproved/Banned/New Drugs Solely for Export Purpose -Reg

NOC's for manufacture of unapproved/banned/new drugs solely for export purpose are granted as per the Guidance Document issued by CDSCO.

The above activity was delegated to State licensing Authorities w.e.f. 20th August, 2018 vide letter of F.No.7-5/2018/Misc./03 4(NOC) dated 2nd August, 2018

Now, it has been decided with the approval of Hon'ble HFM vide Ministry F. No. X.11035/210/2018-DR (Pt) dated 21st June, 2023 that Industry must be facilitated to file fresh applications for NOC for manufacture of unapproved/approved new drug/banned drugs solely for export purpose from15thMay, 2024 on online mode through CDSCO Zonal Offices. Accordingly, power delegated to State/UT Licensing Authority stands withdrawn w.e.f. 15 th May, 2024 and such NOC's shall be granted by the Head of respective CDSCO Zonal office w.e.f.15thMay 2024. Further All State/UT Drugs Controllers are required to handover all NOC's issued from 20th August, 2018 to14thMay, 2024 to respective Zonal Offices of CDSCO.

All manufacturers may be informed that they are required to obtain NOC from respective Zonal Offices of CDSCO through online mode (SUGAM Portal) w.e.f.15th May 2024 before issuing Manufacturing License from SLA for manufacture of Unapproved/Banned/New Drugs for export purpose.

Sh. Ranga Chandrashekar Rao Joint Drugs Controller (India) will be Nodal and designated person at CDSCO, HQ for said activity.

Yours faithfully

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy

1. All Zonal/Sub-Zonal/Port Offices of CDSCO for necessary action.
2. All stake holders through CDSCO website.

Copy for information to:

1. Deputy Secretary (Drug Regulation), MoH F & W, Govt. of India
2. Joint Secretary, (Drug Regulation), MoH F & W, Govt. of India

I/3597641/2023

F.No.X.11035/210/2018-DR (Pt)
Government of India
Ministry of Health and Family Welfare
Department of Health and Family Welfare
(DR Section)

Nirman Bhawan, New Delhi
Dated the June, 2023

To
DCGI, CDSCO, FDA Bhawan,
New Delhi- 110002

Subject: NOC for manufacture of unapproved/banned/new drugs solely for export purpose – regarding.

Sir,

Please refer to your e-file number 8200817 dated 03.01.2023 on subject cited above wherein you have proposed that in supersession of earlier CDSCO order issued vide F. No. 7-5/2018/Misc/034(NOC) dated 2nd August, 2018, a fresh order may be issued requiring that the manufacturer shall take NOC from respective zonal offices of CDSCO before taking manufacturing licenses from SLAs for the manufacture of Unapproved/Banned/New Drugs for export purpose.

2. In this regard, matter has been examined by this ministry and it is to inform you that Industry must be facilitated to file fresh applications for NOC for manufacture of unapproved/banned/new drugs solely for export purpose from **15 May 2024** at a single designated person only on online mode to a point of contact at CDSCO headquarters and the applications can be disposed by CDSCO through their respective zonal offices.

3. Further, CDSCO may give necessary direction to all State/UT drugs controller to hand over details of all such export permissions given by them under the delegated provisions since 2018.

This is issued with approval of Hon'ble HFM

Yours faithfully,

Signed by
(Dr. Kiran Kumar Karlapu)
Deputy Secretary to the Govt. of India
Tele: 011-23062928

Kirankumar Karlapu
Date: 21-06-2023 14:27:43