F. No. 29/Misc/03/2021-DC (28)
Central Drugs Standard Control Organisation,
Directorate General of Health Services,
Ministry of Health and Family Welfare,
Government of India

****

FDA Bhawan, New Delhi
Dated 03.11. 2021

ORDER

Subject: Regulation of CT scan equipment, All Implantable Devices, MRI equipment etc. as Drugs with effect from April 1st, 2021- Regarding.

1. Whereas order of even number dated 18.04.2021 on the subject cited matter was issued by CDSCO (copy enclosed).

2. Whereas the stakeholders have now represented their concerns that due to Covid-19 disruption there is unpreparedness in complying with regulatory requirements within the prescribed timelines, which may lead to disruption of supply chain & access to patients.

3. Now, therefore, in order to ensure smooth transition of manufacturers/importers, continuity of supply chain and access to the patients, with the approval of MoHFW, it has been decided that in case an existing importer/manufacturer who is already importing /manufacturing any of those devices, and whose application has been submitted to the Central License Authority or State License Authority, as the case may be, for grant of import/manufacturing license in respect of the said device(s) under provisions of MDR, 2017 by 18.04.2021, the said application shall be deemed to be valid and the importer/manufacturer, can continue to import/manufacture the said device(s) up to 30.06.2022 or till the time the Central License Authority or State License Authority, as the case may be, takes a decision on the said application, whichever is earlier.

4. Further, the applicant, in case has submitted an incomplete application (submitted by or before 18.04.2021), is required to ensure submission of all the necessary documents to the concerned Authority, by 31.03.2022.

5. Central Licensing Authority or State Licensing Authority, as the case may be, shall dispose of these applications within three months from the date of receipt of complete application.

6. Further, the importer/manufacturer of above said medical devices has to obtain import/manufacturing license for the above said devices by or before 30th June, 2022. The importer/Manufacturer shall necessarily be required to print the import/manufacturing license number on the label with effect from 1st of July 2022.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345df62d489632379a1471bfdae9f0b2bea56c83bfbbe2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.11.03 19:41:40 +05'30'

(Dr V. G. Somani)
Drugs Controller General (India)

To
All States/UTs Drugs Controllers.

Copy to:

1. All Zonal/Sub-Zonal /Port offices of CDSCO
2. All Stakeholders/Associations through CDSCO website