

No. 29/Misc/03/2020-DC (124)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Medical Devices and Diagnostics Division)

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated: 21/8/2020

Notice

Subject: Requirement of fees for change in address of authorized agent, without change in constitution as Post Approval Change under MDR, 2017-reg.

In light of representations received, requesting this office for the removal of the requirement of fees if there is a change in the address of Authorized Agent without change in constitution.

Having examined the representation, it is observed that there is no requirement of fees prescribed in Schedule-VI of MDR, 2017 for post approval changes in case of change in address of authorized agent without change in constitution.

In view of above, the fees may not be required for change of address of authorized agent without change in constitution under MDR, 2017.



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

To,
All stakeholders through CDSCO website.