F.No. D.21013/159/2018-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

FDA Bhavan, Kotla Road,
New Delhi
Dated: 25/x/2018

ORDER

In partial modification of this Organisation's Order of even number dated 20.08.2018, it has been decided that only receipts related to Serious Adverse Events(SAE's) of Clinical trials ongoing in India with which the SAE division is concerned will be accepted by SAE Division situated at Sadiq Nagar, New Delhi.

In other words, the receipts of SAE's including CIOMS/ notifications/SUSAR/Adverse events of marketed drugs occurring outside India and SAE reports of PMS/PSUR/Academic trials/observational/Non-interventional studies of marketed products will not be accepted by SAE division situated at Sadiq Nagar with immediate effect and the same will be accepted by CRU, FDA Bhavan, New Delhi for processing by the concerned divisions.

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(Vum Mang)
Dy. Director (Administration)

Copy to:

(i) All JDC(I)/DDC(I) in CDSCO(HQ)
(ii) DDC(I), SAE Division, Sadiq Nagar, New Delhi
(iii) CRU, FDA Bhavan, New Delhi
(iv) O/o DCG(I)
(v) Website
(ii) Guard File