بسم الله الرحمن الرحيم

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
(255)
Office of Vice President for Medical Devices Sector

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
(٢٥٥)
مكتب نائب الرئيس لقطاع الأجهزة و المنتجات الطبية

Measures related to the failure to notify the National Center for Medical Devices Reporting –NCMDR of any medical devices field safety notices

Dear Local Manufacturers and their Authorized representatives

Dear Authorized Representatives of foreign manufacturers,

Further with the previous announcement for the necessary need to notify SFDA of the Field safety notices/recalls - that was published on the SFDA website on 20/6/1439 H; -

SFDA announces the commencement of measures related to the failure to notify the National Center for Medical Devices Reporting –NCMDR of any medical devices field safety notices within a period of two calendar days they aware of through the manufacturer or via counterpart regulatory authority website, where the measures will be applied on Local Manufacturers –or their Authorized Representatives- and Authorized Representatives of foreign manufacturers as the following:

- Failure of notification or noncompliance for the first time: SFDA will send a warning letter via email.
- Failure of notification or noncompliance for the Second time: Suspension of AR Certificate for two weeks
- Failure of notification or noncompliance for the Third time: Suspension of AR Certificate for four weeks
- Failure of notification or noncompliance for the Fourth time: The case will be transferred to the Vice President for Medical Devices for further regulatory action.

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