

F.No. 12-01/19-DC(PT-195)

Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
Office of Drugs Controller General (India)  
(New Drugs Division)

FDA Bhawan, Kotla Road,  
New Delhi-110002  
Date: 21/2/2020

**NOTICE**

**Subject: Sub-acute toxicity study report for injectable products for BA/BE study in human for export - reg.**

CDSCO receives and process application for permission to conduct BA/BE study in human for export.

Concerns have been raised that sub-acute toxicity study report in at least two species for minimum 14 days is required to be submitted for innovator products.

In this regard, it is clarified that sub-acute toxicity data for innovator products are neither required nor asked for conduct of BA/BE study in human for export.

Yours faithfully,



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

To,

1. All Stakeholders.