F. No. 12-01/22-DC (Pt-142)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road
New Delhi- 110002
Dated: 7/7/2022

To

All Zonal/Sub-Zonal/Port Offices of CDSCO

Subject: Clarification regarding import of non-drug / lab kits shipments related to clinical trial / clinical research purposes

Sir,

This office has received representation regarding challenges being faced by sponsors conducting clinical trial / clinical research in importing of ancillary items including non-drug items / lab kits / equipment / accessories etc. which are necessitated for conducting clinical research / clinical trial as per approved protocol.

In this regard, for encouraging research and clinical development and for streamlining the import of such items, the sponsor / importer may submit an undertaking along with the copy of clinical trial / clinical research approval obtained by sponsor / importer, at the concerned Port Office of CDSCO stating that such imported items are being imported and will be used for clinical trial / clinical research purpose only and will not be diverted for any other purposes, as per applicable rules, based on which such import consignments may be cleared at the port of import.

Yours Faithfully,

V.G.S.

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