Import / Misc/89/2015-DC

Directorate General of Health Services

Central Drugs Standard Control Organisation

(Import & Registration Division)

FDA Bhawan, NewDelhi.

Dated

Order

In light of bringing ease in regulatory clearance without compromising the quality issues on the consignment entering into the Indian market, it has been decided to have 'Risk based criteria for sampling of imported consignment under Drugs and Cosmetics Rules, 1945', the details of which is appended below:

1. Random sampling of any one consignment in six months or of any one consignment in sequential 10 consignments, whichever is earlier is to be done.
2. Imported product & consignment, if from ICH countries (USA, EU, Australia, Japan, Canada) and being imported since last 5 years without any complaint/quality failure in testing of the samples drawn, the frequency of sampling is to be reduced to any one consignment in two years or to any one consignment in sequential 20 consignments, whichever is earlier.
3. If the sample of any product has failed then, sampling has to be done on subsequent 5 consecutive consignments of the product.
4. If the product is from a new source, it has to be sampled for testing.
5. If the information/ evidences are received by Port officer of CDSCO/ Custom officer about doubtful quality of the product, it has to be sampled and tested.

You are hereby directed to adhere with above criteria and submit performance based report quarterly.

(Dr. G.N.Singh)
Drugs Controller General (India)

To
All Zonal/Subzonal/Port offices of CDSCO

Copy for information to:
Sh. S.P.Sahu – Customs Commissioner (Single Window)