

Government of India
Ministry of Health & Welfare
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi, dated 6th February, 2017

NOTICE

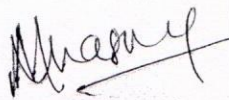
Subject:- Ease of Doing Business relating to export of Drugs - Reg.

In keeping with the existing focus of the Central Govt. on taking relevant steps to facilitate the ease of doing business, the CDSCO proposes to make the following services online through SUGAM Portal w.e.f. 1st March, 2017:-

- (i) Seeking written Confirmation issued by CDSCO for export of API to European Union (350 Nos.) and
- (ii) Certificate of Pharmaceutical products (COPP) issued jointly by State and CDSCO (1550 Nos. approx.).

2. Further, the Risk Based Inspections will be carried out by the Centre and State with definite tools as reflected in the Risk Based Document prepared by CDSCO. However, the applicants would mandatorily submit the details of observations made during self-inspection and follow any other overseas regulatory bodies or as decided by Central and State Regulator from time to time.

3. Wherever extra inspections are required, the reasons for doing the same will have to be stated to the satisfaction of the higher ups of the concerned Central or State Regulator.


(Arun Sharma)
Director(Admn)

To

Joint Drugs Controller(I), CDSCO(HQ).

Copy to:-

- (i) PPS to JS(R), MoHFW.
- (ii) Joint Secretary, Deptt. of Pharmaceuticals.
- (iii) Joint Secretary, Deptt. of Commerce.
- (iv) Website of CDSCO.

CC: Pharma Associations for information.