File No. ED/Misc.-244/2018-D
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Enforcement Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Email: dci@nic.in
Phone: 011-23236965
Dated: 08.12.2018

To,

All States/UTs Drugs Controller

Subject: Submission of Stability Data before grant of licence for drugs including Large Volume Parenteral – **reg.**

Sir,

As you are aware that in 53rd meeting of Drugs Consultative Committee held on 09.04.2018, it was agreed that manufacturer are required to ensure the stability of all drugs manufactured by them before grant of Licence so that patient get quality medicines as per G.S.R. 360 (E), Rule 71, 71b and 76 which states that "the applicant shall, while applying for Licence to manufacture Drugs, furnish to the licensing authority evidence and data justifying that the drugs are stable under the conditions of storage recommended".

Accordingly you are requested to ensure that all the manufacturers are required to submit stability data along with application for all the drugs including Large Volume Parenteral before grant of licence.

This is for your information and necessary action.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Copy to:-
All Zonal/ Sub-zonal offices of CDSCO: with the direction to ensure that inspection team shall ensure the stability data of drugs covered under CLAA scheme has been generated by all the manufacturers before it is recommended for grant of licence.

circulate to all DI's on immediate basis.

11/12/2018