File No. 7-5/2016/Misc./041
Directorate General of Health Services
Central Drugs Standard Control Organization
(O/o Drugs Controller General India)

FDA Bhavan, Kotla Road,
New Delhi-110002
Date: 09-08-17

NOTICE

Issues related to universal adoption of Good Manufacturing Practices (GMP) by pharmaceutical sector and to explore the possibility of self certification by the pharmaceutical units followed by third party certification followed by detailed audit have been deliberated at the highest level.

In this regard, it may be mentioned that, CDSCO had earlier prepared a detailed checklist for all manufacturing facilities to comply with the requirements of Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) as specified under Schedule M and Schedule L-1 of the Drugs and Cosmetics Act and Rules there under. The checklist includes an elaborate tool kit for verification of GMP/GLP along with benchmarks based on the concept of rating manufacturing units on the basis of an estimated risk that they may pose to users of medicines. This checklist was devised with a view to ensure that each manufacturing unit carries out self assessment to GMP/GLP compliance.

All drug manufacturers and pharmaceutical associations were requested vide notice no. 7-5/2016/misc/041 dated 23.07.2015 to make self assessment of their manufacturing units as part of their self audit and mandatorily share their reports with State Licensing Authorities and CDSCO. However, CDSCO is yet to receive self inspection reports from the manufacturers.

In view of above, all drug manufacturers are requested to submit the report of self assessment of their units along with self certification stating that they are complying with GMP/GLP requirement as per Drugs and Cosmetic Rules, to the State Licensing Authorities and CDSCO by 30.08.2017.

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

To:

1. All Drugs Manufacturers
2. All Pharmaceutical Associations