

Ref. No:

Date:

To

The Drugs Controller General (India)
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road
New Delhi-11002

Your show cause notice number _____ dated _____

Dear Sir,

We have received your show cause notice for cancellation of FDCs. On your directives we applied on form 44 along with requisite fees and data in your office to prove safety and efficacy of FDC's which were not approved by you but approved by SDC. FDC were applied in your office before the grant of relief from Hon'ble High Court of Punjab and Haryana High Court.

Sir, as you are aware that Haryana Pharmaceutical Manufacturers Association has filed a writ petition in Punjab & Haryana High Court and on 23rd October 2013, the Hon'ble court was please to pass the stay order, the operative part thereof read thus:

"In the meantime, respondents are directed not to take coercive action against the petitioner for compliance of the impugned letters, till the next date of hearing."

Even in the similar matter, the Hon'ble High Court of Himachal Pradesh in CWP-7863/2013, vide its order dated 27.09.2013, granted ad-interim stay and further it was made absolute till the final disposal of the petition.

Therefore in view of the above mentioned facts the matter is still in sub-judice, as soon as the outcome from both the High Courts i.e. Himachal Pradesh High Court and Punjab & Haryana High Court announced, we will submit a suitable reply of your show cause notice.

For _____

Authorised Signatory