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PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Setup by Ministry of Commerce & Industry, Govt. of India)

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HO/DCGI/3321

Date: 18.1.2010

Dr. Surinder Singh
Drug Controller General of India
The Drug Control General of India
NEW DELHI
Fax: 011 23062648

Dear Sir,

Sub: Labeling norms for Pharma Industry

We refer to the news item appeared in the press on the above subject, wherein it is mentioned that DCGI is contemplating to regulate the labeling procedures by insisting to display the label contents in English translation also, if it is in other language. While we appreciate the efforts of DCGI which are in the best interest of country's image in the international markets, some of our members expressed their concerns, which we would like to bring to your kind notice.

The main concern of our members is that on which label the translation is to be printed i.e. whether it is on the primary packaging (on the vial / ampoules / tablets pack or it is on the outer container. Also, since products are registered as per labeling conditions of importing countries, any change in the format of the label format may not be accepted by the importing country unless it is again approved, which takes considerable time.

As we understand from the news item that formulation of revised procedures for labeling is yet to be completed, we request that Pharmexcil / industry views may be invited before final notification is issued so that pharma exports are not affected adversely.

We take this opportunity to refer to the meeting on 12.1.2009 with Joint Secretary, Dept. of Commerce, wherein you have kindly accepted to involve Pharmexcil in major policy issues. We would be happy to extend all possible assistance for the benefit of pharma industry in India.

Thanking you,

Yours sincerely,

P. V. APPAJI

Dr. P V APPAJI
EXECUTIVE DIRECTOR

copy to Sni Rajeev kher, Joint Secretary, Dept. of Commerce

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