

**4. Current status of cartons, label of inner most container of the drug and other covering in which container is packed**

1) In form 45, under "conditions or for grant of approval/ permission",-

For condition (2), the following condition shall be substituted, namely:-

"(2) The proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written below or after the proper name on the label of the innermost container of the drug or every other covering in which the container is packed.";

2) In condition (3), for the words "conspicuous red vertical line on the left side running throughout the body of the label which shall not be less than 1 mm in width and", the words "caution or warning, as applicable, depending on whether the drug is covered under schedule G or Schedule H or schedule H1 or schedule X, as specified in rule 97, in legible black colored font size in a completely red rectangular box" shall be substituted.

3) In form 46, under "conditions or for Grant of Approval / permission",-

For condition (2), the following condition shall be substituted,

Namely:-

"(2) The proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written below or after the proper name on the label of the innermost container of the drug or every other covering in which the container is packed."

4) In condition (3), for the words "conspicuous red vertical line on the left side running throughout the body of the label which shall not be less than 1 mm in width and", covered under schedule G or Schedule H or schedule H1 or schedule X, as specified in rule 97, in legible black coloured font size in a completely red rectangular box" shall be substituted.