

File No. X-11026/143/16-BD  
Directorate General of Health Services  
Office of Drugs Controller General (India)  
(Biological Division)


DATED: 13-12-2016

**OFFICE MEMORANDUM**

**Subject:** Timelines for CDL Kasauli to review and processing of applications referred for CMC or post approval change- Regarding

In order to streamline the process of review within the stipulated timelines, it is decided that CDL Kasauli will issue their comments within thirty working days to CDSCO. Further, if any queries are raised by CDL Kasauli on behalf CDSCO, the applicant shall submit its response not later than 30days.

If the applicant fails to provide the requisite information /documents/clarifications sought by the CDL Kasauli on behalf of CDSCO within prescribed time line, then it will be presumed that the firm is not interested in pursuing the application and shall be treated as terminated for further processing, unless otherwise justified and permitted by the Licensing Authority under 21(b) of Drugs and Cosmetics Rules.

  
(Dr. G. N. Singh)

**Drugs Controller General (India)**

**To:**

**Director,  
Central Drugs Laboratory, Kasauli  
All Zone/Subzone Offices of CDSCO**