

FILE No. DCG (I)/MISC/2016 (85)
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/O DRUGS CONTROLLER GENERAL INDIA)

DATED: 13TH JULY, 2016

NOTICE

While reviewing the pendency status of applications relating to grant of various licence/approval/permissions, etc., it has come to the notice of CDSCO that in a large number of cases where CDSCO had requested the applicant to submit further technical details/ clarifications, etc., the applicants do not respond within a reasonable time and submit their responses to CDSCO. This causes undue delay in the disposal of applications by CDSCO.

2. In view of the above, it is proposed that in cases where an applicant fails to submit the requisite clarification to CDSCO within 45 days of seeking the information and does not seek extension for submission of such information, it will be presumed that the applicant does not intend to pursue its application further and it would be disposed of based on the merit of the application.

3. With a view to expedite decision making and facilitate speedier clearances, a system has been established whereunder all applicants could seek an appointment with the concerned Joint Drugs Controller (India) or Drugs Controller General (India) in cases, where the applications submitted by them are not disposed of within 2/3rd of the time-lines specified for the purpose.


(DR. G. N. SINGH)

DRUGS CONTROLLER GENERAL (INDIA)

To

IDMA/OPPI/IPA/FOPE/CIPI/BDMA

COPY TO:

ALL JDC (I)/DDC (I)/ADC (I), CDSCO HQ

COPY FOR INFORMATION TO:

PPS TO DGHS/AS (F&D)/JS (R), MINISTRY OF HEALTH & FAMILY WELFARE