File No. DCGI/MISC/2016 (36)
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standards Control Organization

FDA Bhavan, Kotla Road,
New Delhi-110002.
Dated: 29th March, 2016

OFFICE MEMORANDUM

In order to ensue strict adherence to the timelines and timely disposal, the pending applications pertaining to Global Clinical Trial/New Drug Approval/Medical Devices and other matters which require evaluation by the Subject Expert Committees be disposed of within three weeks' time to reach to the zero level pendency.

In case of submission of reply by an applicant against any query, the officer concerned at the pre-screening level should verify whether the applicant has replied to the query without going through evaluation at her/his level to decide its acceptability. The content of the reply will be evaluated by the concerned Division of CDSCO in consultation with the Subject Expert Committee wherever applicable.

In case of any application, where queries have been raised twice consecutively on the same matter considering that the replies submitted by the applicant have not addressed the queries, while processing the third reply, the concerned file should be submitted to the undersigned before raising further query.

(Dr. G.N. Singh)
Drugs Controller General (India)

To

1. JDC (ER)/JDC (VGS), CDSCO HQ
2. All DDC (I), CDSCO HQ
3. Director (Admn.), CDSCO HQ
4. I/c Pre-screening Desk
5. Guard file