

File No. IT-11011(11)/1/2026
CENTRAL DRUGS STANDARD CONTROL ORGANISATION
(Directorate General of Health Services)
Ministry of Health & Family Welfare

FDA Bhawan, ITO, Kotla Road,
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367,
Fax No.: 91-11-23236973

Date: **16 JAN 2026**

PUBLIC NOTICE

Subject: Disposal/Rejection of Long-Pending Applications on SUGAM Portal Awaiting Query Response-regarding.

It has been observed that applications across various divisions are pending at the applicant's end due to non-submission of responses to queries raised.

In order to reduce the backlog of long-pending applications awaiting query responses across various divisions, namely Subsequent New Drugs, Investigational New Drugs, New Drugs, Fixed Dose Combinations, Import, Cosmetics, Biologics (applications pending since 2016) and Medical Devices and In Vitro Diagnostics (applications pending since 2018), the Central Drugs Standard Control Organization (CDSCO) has initiated a structured reminder mechanism for applicants who have submitted applications through the SUGAM portal.

As part of this mechanism, CDSCO issues reminders at fixed intervals to inform applicants to respond to the pending queries raised during the evaluation of their applications. A series of three reminders is sent to the applicants, requesting them to submit responses to the pending queries within the prescribed timelines, as detailed in the Annexure attached to this notice.

Applicants who fail to respond to the pending queries through email and the SUGAM portal even after issuance of the three reminders are subsequently issued a fourth and final communication, informing them that their application stands rejected, with the fee amount forfeited, in accordance with the applicable provisions.

In this regard, all stakeholders are hereby informed that applications pending with applicants for more than two years have already been notified through the three-reminder process, shall now be rejected after a period of

30 days from the date of issue of this public notice. A final rejection communication shall be issued accordingly to the concerned applicants.

All stakeholders are advised to ensure that all pending queries are addressed within the stipulated time period to avoid rejection of their applications.


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To,

All stakeholders

Copy to:

- i. All JDC(I)s, DDC(I)s in CDSCO(HQ)
- ii. Staff of DCGI
- iii. Notice Board
- iv. CDSCO Website
- v. PRO Cell
- vi. All Zones and Port Offices

Annexure:

Timeline for reminders to be sent for old applications for their disposal

- 1st Reminder (Customized) on old files
- 2nd Reminder = 1st reminder + 30 days
- 3rd Reminder = 2nd reminder + 30 days
- 4th Disposal Notice = 3rd reminder +30 days