CDSCO

CDSCO widens rejection of SUGAM applications awaiting replies

CDSCO's May 4, 2026 notice adds divisions including GCT, BABE, Ethics Committee and Veterinary to its reminder and rejection process for SUGAM applications.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare, issued Public Notice IT-11011(11)/16/2026, dated May 4, 2026. Its subject is "Disposal/Rejection of Long-Pending Applications on SUGAM Portal Awaiting Query Response". It is signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India), and addressed to all stakeholders, with copies to the JDC(I)s and DDC(I)s at CDSCO headquarters, the staff of the DCGI, the notice board, the CDSCO website, the PRO Cell and all zones and port offices.

KEY FACTS

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The notice says applications across various divisions are pending at the applicant's end because responses to the "queries" raised have not been submitted. To reduce this backlog, and in continuation of the office order released on January 16, 2026, File No. IT-11011(11)/1/2026, CDSCO has started a structured reminder mechanism in "more divisions including GCT, BABE, Ethics Committee and Veterinary (applications pending since 2016)" for applications submitted on the SUGAM portal. The January 16, 2026 document under that file number, headed "Public Notice", covered Subsequent New Drugs, Investigational New Drugs, New Drugs, Fixed Dose Combinations, Import, Cosmetics and Biologics (applications pending since 2016) and Medical Devices and In Vitro Diagnostics (applications pending since 2018).

CDSCO sends three reminders asking applicants to respond to the pending "queries" raised during the evaluation of their applications. Under the notice's Annexure, the first is a customized reminder on old files, the second follows 30 days after the first, the third 30 days after the second, and a fourth, a disposal notice, 30 days after the third. An applicant who still does not respond through email and the SUGAM portal after the three reminders receives that fourth and final communication, saying the application stands rejected, with the fee amount forfeited, in accordance with the applicable provisions.

The notice informs all stakeholders that applications pending with the applicants for more than two years "have already been notified through the three-reminder process" and are to be rejected after a period of 30 days from the date of issue of the notice, May 4, 2026. A final rejection communication is to be issued to the applicants concerned. The notice asks all stakeholders to address all pending "queries" within the stipulated time to avoid rejection, and to review the Annexure for the prescribed timelines applicable to specific forms.

The Annexure, headed "Days calculations for sending series of reminders", gives only the reminder intervals; it names no forms and no form-specific timelines. The notice does not spell out GCT or BABE, and, by saying "including", it does not list every division the mechanism now covers. It does not name the provisions under which the fee is forfeited, and it does not say whether an applicant whose application is rejected may apply again.

Issued by	Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare
Document	Public Notice IT-11011(11)/16/2026
Dated	May 4, 2026
Subject	"Disposal/Rejection of Long-Pending Applications on SUGAM Portal Awaiting Query Response"
Applies to	Applications on the SUGAM portal awaiting the applicant's response to "queries", in more divisions including GCT, BABE, Ethics Committee and Veterinary (applications pending since 2016)
Continues	The office order released on January 16, 2026, File No. IT-11011(11)/1/2026, which covered other divisions
Reminders	First (customized) on old files; second 30 days after the first; third 30 days after the second
Disposal notice	30 days after the third reminder: the application stands rejected, with the fee amount forfeited
Pending with the applicant over two years	Said to have "already been notified through the three-reminder process"; to be rejected after 30 days from the date of issue of the notice, with a final rejection communication
Signed by	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India)

The public notice (PDF, 779 KB)

Source: CDSCO's own copy.

Checked against the official copy on October 28, 2026.

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