Medicines & Healthcare products Regulatory Agency

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Dr Rinat Ezra
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UNITED KINGDOM

08/10/2026

Dear Dr Rinat Ezra,

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031 ("the Regulations")

Our Reference	CTA 19174/0439/001-0006
IRAS ID	1005848
Product	Sargramostim (Leukine)
Protocol number	A4-1- 22SM8039
Substantial Modification Code Number	AM013

NOTICE OF ACCEPTANCE OF SUBSTANTIAL MODIFICATION

This letter refers to your modification request received on 02/09/2026.

The licensing authority accepts the proposed substantial modification to your clinical trial authorisation (CTA), including the labelling, subject to any conditions.

COMBINED REVIEW MEDICAL

You are reminded that, where appropriate, a favourable opinion from the ethics committee is also required before this modification can be made (please refer to the Modification Tool outcome).

Please ensure that the public registry where you have registered your trial has been updated to reflect any relevant changes.

Yours sincerely,

Clinical Investigations & Trials
MHRA