

REGULATION AND PREQUALIFICATION DEPARTMENT

VACCINES ASSESSMENT TEAM

TEMPLATE

STANDARD LETTER A - NOTIFICATION OF PROBLEMS IDENTIFIED DURING PRODUCT RE-EVALUATION

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Dear Sir/Madam,

Notification of problems identified during product re-evaluation. Your reference:

We refer to cproduct/device description> which is currently listed on the PQS database.

We write to advise you that at the recent

EITHER:

<annual product review >

OR:

<extraordinary product review>

a number of concerns regarding this item of equipment came to light. These concerns are as follows:

concerns>

At present, the PQS prequalification status for this product will be maintained. However, we would be grateful if you would comment on the problems we have identified and provide us with a timetable for their resolution.

Meanwhile, if you have any queries, please contact the writer.

Yours faithfully,