

REGULATION AND PREQUALIFICATION DEPARTMENT

VACCINES ASSESSMENT TEAM

TEMPLATE

STANDARD LETTER C - REQUEST FOR MISSING INFORMATION

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Standard letter C - Request for missing information

Dear Sir/Madam,

Application for prequalification of a product or device under the IMD-PQS system. Your reference:

We refer to your letter dated <dd.mm.yy> with regard to product/device description>,
enclosing the Product Dossier requested in our letter dated <dd.mm.yy>.

We have now made a preliminary examination of the Product Dossier and find that the following material is missing:

list missing information, samples, etc.>

If we do not receive the missing items by <dd.mm.yy> we will have to reject your application. The Dossier will then be returned to you but we will not be able to return the Dossier Examination fee.

If you have any queries, please contact us as soon as possible.

Yours faithfully,

