[text to be included in the cover letter of the submission requesting the change of applicant]

We herewith **request to change the applicant** for this application from <name and address of the current applicant> to <name and address of the future applicant>.

We hereby confirm that:

* this application does not fall under the scope of a duplicate application as per Article 82 of Regulation (EC) No 726/2004; *[Note: if this is not confirmed the relevant authorisation from the European Commission needs to be included in Annex 5.16 to the Application form.]*
* complete and up-to-date file concerning the medicinal product or a copy of this file (including any data/documents related to the paediatric obligations, if applicable) has been made available to or has been transferred to the new applicant;
* the orphan designation has been transferred; *[if applicable]*

As a result of the change of applicant, we have amended the following parts of the Application Form: <list of the (sub)sections and annexes of the application form that have been updated>.

|  |  |
| --- | --- |
| On behalf of the current applicant:<Signature, name, surname and function of the person authorised to communicate on behalf of the current applicant> | On behalf of the new applicant:<Signature, name, surname and function of the person authorised to communicate on behalf of the new applicant> |