**Letter of Authorization**

See the next page for the template. Information to be filled in, including notes about that information, is in brackets.

Date: [Enter the date of this submission]

DMF#: [Enter the DMF number]

Holder: [Enter the DMF holder’s name]

Subject (Title): [Enter the subject (title) of the DMF as it appears on the DMF List, available on the DMF web site at<https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs>]

Submission Type: Letter of Authorization

Statement of Commitment: [The following statement of commitment, signed by the DMF holder, should be included in this letter or separately in eCTD section 1.2. If included in eCTD section 1.2, mention that here (e.g., “See eCTD section 1.2 for statement of commitment”).]

[DMF HOLDER] states that [DMF NUMBER] is current and [DMF HOLDER] will comply with the statements made within it. [DMF HOLDER] will notify FDA through an amendment to [DMF NUMBER] of any addition, change, or deletion of information in the DMF. [DMF HOLDER] will also notify [AUTHORIZED PARTY] in writing that an addition, change, or deletion of information has been made to the DMF as required by 21 CFR 314.420(c).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of DMF holder

Dear DMF staff:

[DMF HOLDER] authorizes [AUTHORIZED PARTY] to incorporate by reference information regarding [ITEM] in [DMF NUMBER] into any application filed by [AUTHORIZED PARTY]. [DMF HOLDER] also authorizes FDA to review this information in [DMF NUMBER] when considering any application filed by [AUTHORIZED PARTY].

[Provide the name of the specific products, items, or processes to be referenced, or the entire DMF where applicable, by the authorized party. Include the submission date, section numbers, and page numbers.

Provide the name of the authorized party (one party per LOA).

Additionally, we recommend including the type (e.g., new drug application, investigational new drug application) and number of applications or other DMFs referencing the DMF.]

Sincerely,

[Signature of responsible official]

[Name of responsible official]

[Responsible official’s title]

[Responsible official’s company (i.e., DMF holder or agent)]

[Responsible official’s telephone number]

[Responsible official’s fax number]

[Responsible official’s email address]