**Cover Letter: Subsequent Submissions**

This cover letter template is for subsequent submissions (e.g., amendments, LOAs) and annual reports.

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]

DMF Type: [Enter the DMF type (Type II, III, IV, or V)]

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: [Enter the applicable submission type (e.g., administrative amendment, quality amendment, LOA, annual report) as listed in the DMF Submission and Amendment Types table on the DMF web site. If multiple submission types are submitted at the same time, list each here. Narrow amendments down by type, as needed (e.g., change of DMF subject (title)).]

Dear DMF staff:

[Provide additional information about the DMF not captured in above (e.g., a brief description of content changes, the dates and eCTD sections or page numbers of previous submissions affected by the change, a statement confirming that authorized parties have been notified of changes as required by 21 CFR 314.420(c) and the date of the notification). The cover letter for an amendment responding to a letter from FDA should specify the date of FDA’s letter, the issues raised in that letter, and the DMF holder’s responses. Detailed responses can be included in eCTD section 1.11.]

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]