**Cover Letter: Original Submission**

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 requested DMF type (Type II, III, IV, or V)]

Subject (Title): [Enter the subject (title) of the DMF\*]

Submission Type: Original (New)

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:

[Provide additional information about the DMF not captured in the header.]

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]

[\* Type III or IV DMFs that are being submitted for a number of different items of the same type, e.g., different HPDE bottles, can be submitted with a general subject, e.g. “Plastic HDPE Bottles for Pharmaceutical Use.”

\*\*If the DMF is being submitted by an agent on behalf of the holder, there should be an agent appointment letter signed by the holder included in the submission and the agent should be listed in the administrative section of the DMF.]