DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

INSTRUCTIONS FOR FILLING OUT FDA FORM 3938 – DRUG MASTER FILE (DMF)

(The field numbers below correspond to the numbered boxes on the FDA Form 3938)

NOTE: Please submit a new FDA Form 3938 with each submission. Complete the fields of the form sequentially. (For more information on the various types of DMFs, see Guidance for Industry: Drug Master Files, CDER DMF website and Master Files for CBER-Regulated Products website. This Form can be used for CDER DMF and CBER MF submissions that support application types such as IND, NDA, BLA and ANDA.

Field 1: DATE

Enter the date the submission is being submitted using the format mm/dd/yyyy.

Field 2: DMF NUMBER

Provide the six-digit DMF number. For DMF numbers less than six digits, the DMF number should be preceded by zeros to make it six digits (i.e., for DMF 12345 enter 012345).

Field 3: DMF SUBJECT

Enter the Subject (Title) of the DMF. This information will be publicly available.

Field 4: DMF TYPE

Select One Applicable DMF Type

- Type II Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation, or Drug Product
- Type III Packaging Material
- Type IV Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation
- Type V FDA Accepted Reference Information, REMS

See 21 CFR 314.420

Field 5: DMF HOLDER INFORMATION

Include the name, DUNS number and address of the DMF Holder. If DUNS number is unknown or not available, enter “999999999” (9-digits). Only one entity can be the DMF holder. The holder is expected to be the manufacturer. If the DMF holder is not the manufacturer, the DMF should include a signed statement from the holder stating that the DMF holder assumes responsibility for the manufacturing of the material covered by the DMF.

Enter the name, telephone number, email address and fax number of the contact person at the holder company.

Field 6: DMF AGENT OR HOLDER REPRESENTATIVE AT ALTERNATE ADDRESS

Include the name and address of the person or legal entity who has been appointed by the DMF holder as their DMF Agent. Although there is no regulatory requirement for DMF holders to appoint an agent, this is recommended for DMFs submitted by holders located outside the United States. If the DMF holder company assigns one of their employees as the contact person and that contact person is not located at the holder address, they are considered a holder representative. Include their information in this field as representative.

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If the Responsible Official (See **Field 11**) is the Agent or is employed by the Agent this should be specified in the Agent Appointment Letter.

Enter the company name, address, contact person name, telephone number, email address and fax number of the agent or holder representative.

Field 7: SUBMISSION TYPE

Choose the Submission Type(s) that apply. A submission can contain more than one Submission Type.

a. **Original (new)** – A submission to establish a new DMF, that includes administrative and technical information appropriate for the DMF Type selected in **Field 4**.

b. **Administrative Amendment** – A submission that contains changes to administrative information (e.g. DMF Holder name, address, subject, agent).

c. **Annual Report** – An annual submission identifying list of amendments (with date), if any, submitted to the DMF in the last 12 months (there is no need to re-submit the amendments), a list of all parties whose authorization remain in force, a list of parties whose authorization has been withdrawn or a statement stating no amendments submitted and/or no authorized parties, and a holder signed statement of commitment. The annual report is not to be used for purposes of reporting new changes to a DMF. The annual report is required to maintain a DMF status of "active".

d. **Letter of Authorization** – A submission from a DMF holder/agent that grants the Authorized Party to incorporate the information in the DMF by reference and grants FDA authorization to review the DMF.

e. **Withdrawal of Letter of Authorization** – A submission which notifies a withdrawal of authorization to a party for whom a letter of authorization was previously submitted.

f. **Meeting** – A formal request or supporting information for a meeting with the FDA.

g. **Quality Amendment** – A submission that contains changes to the chemistry, manufacturing and control information, also referred to as a technical amendment.

h. **Response to Administrative Filing Issue** – A response to an Administrative Filing Issue Letter from the FDA with a requested information.

i. **Response to Deficiency, Complete Response, Information Request or Additional Comments Letter** – This incorporates Response to Deficiency, Complete Response, Information Request or Additional Comments Letter from the FDA requesting a change to the information in the DMF.

j. **REMS** – Risk Evaluation and Mitigation Strategy – A submission that contains information for shared system REMS submissions, also referred to as technical information.

k. **Other** – A submission containing information that is not captured by any other **Field 7** category, for example, DMF Closure.

Field 8: AMENDMENT TYPE

Choose the Amendment Type(s) that apply(ies). A DMF amendment is a submission reporting any change to the previously submitted information. Select all that apply.

a. **Change of agent/address/contact person** – amendment notifying of any change to the agent company, address, and/or contact person information (Note: This would require a new Agent Appointment Letter).

b. **Change of holder/address/contact person** – amendment notifying of any change to the holder company, address, and/or contact person information.

c. **Change of DMF Subject (title)** – amendment notifying of any change to the subject (title) of a DMF.

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d. **Change of DMF Type** – amendment notifying of any change to the type/classification of a DMF.

e. **Meeting Package** – Contains information to support meeting(s) with the FDA.

f. **Meeting Request** – A formal meeting request with the FDA.

g. **Controls Information** – a change to the manufacturing controls in the DMF.

h. **Facility Information** – a change to the facility information in the DMF.

i. **Formulation Information** –a change to the formulation of the item(s) in the DMF.

j. **Manufacture Information** – change to the manufacturing process information in the DMF.

k. **Microbiology Information** – Change to the microbiology and sterility assurance information in the DMF.

l. **New Item** – Additional item or component added to the DMF. This is used primarily for Type III & IV DMFs.

m. **Packaging Information** – Change to the packaging information in the DMF.

n. **Stability Information** – Change to the stability information in the DMF.

o. **REMS Final** – submission contains the final REMS document, all REMS materials in their final format, and the final REMS supporting document.

p. **REMS Assessment** – submission contains the REMS assessment report(s).

q. **REMS Assessment Methodology** – submission contains the proposed methodologies that will be used to assess the REMS.

r. **REMS Revision** – submission contains proposed changes to the REMS that meet the criteria for REMS Revision.

s. **REMS Modification** – Due to Safety Labeling Changes – submission contains proposed changes to the REMS due to safety labeling changes.

t. **REMS Modification-Major** – submission contains proposed changes to the REMS that meet the criteria for a major modification.

u. **REMS Modification-Minor** – submission contains proposed changes to the REMS that meet the criteria for a minor modification.

v. **REMS Proposal-Standard** – submission contains proposed REMS document, all REMS materials, and the REMS supporting document.

w. **REMS Correspondence** – A correspondence about a shared system REMS that is not associated with a submission. Responses to FDA "Requests for Information or Comments," that are associated with a REMS submission should be included under the applicable Amendment Type. A submission that only includes the REMS supporting document should be submitted as a REMS correspondence.

x. **Agent Appointment** – A letter from a DMF Holder appointing an agent to a DMF.

y. **Other** – A submission containing information that is not captured by any other **Field 8** category.

Field 9: ESTABLISHMENT INFORMATION

Include complete Establishment Information for Type II [Active Pharmaceutical Ingredients (APIs), API intermediates, drug products or drug product intermediates], Type III [sterile processing facilities only] or Type V [sterile processing or biotech facilities only] DMFs. For Type II API and Drug Product DMF

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establishments, include manufacturing site and testing sites that perform release and stability testing. **Do not include** Establishment Information for manufacturers of packaging materials or excipients in this field.

If no establishment information leave this Field blank.

Provide the establishment name, address (P.O. Box is NOT acceptable), establishment DUNS number and registration (FEI) number for each manufacturing, packaging, and control site described in the DMF. If DUNS or FEI number is unkown or not available, enter “999999999” (9-digits) in the DUNS field and “9999999999” (10-digits) in the FEI field.

Indicate whether the establishment is new for this DMF.

For “Establishment Role”, provide a general description of the specific activity (e.g. drug product manufacturing, drug substance manufacturing, testing, packaging) conducted at the establishment.

Indicate whether the establishment is ready for inspection. If not, indicate when it will be ready.

Provide the name, telephone number, email address and fax number of the contact person at the site.

Use the ‘Add Establishment’ button as needed. If added inadvertently, click on the Delete Page button at the bottom right of the form.

Field 10: REFERENCED DMF(S)

This section should list all DMFs that are referenced by the current DMF. Include the DMF number, subject (title) of the DMF, and the DMF holder name.

Fields 11–17: CERTIFICATION

Field 11. Enter the name and title of the Responsible Official. The Holder company’s contact person named in **Field 5** or the Appointed Agent company’s contact person or Holder Representative named in **Field 6**.

Field 12. Enter the date the Form is being signed.

Fields 13–15. Enter the telephone number, FAX number, and email address of the Responsible Official named in **Field 11**.

Field 16. Enter the address of the Responsible Official named in **Field 11**.

Field 17. The Form must be signed in **Field 17** by the Responsible Official named in **Field 11**.