Type V DMFs for CDER-Led Combination Products Using Device Constituent Parts With Electronics or Software

Guidance for Industry

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

October 2019
Pharmaceutical Quality/CMC

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Type V DMFs for CDER-Led Combination Products Using Device Constituent Parts With Electronics or Software Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

A drug master file (DMF) is a voluntary submission to FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. The draft guidance for industry *Drug Master Files* (October 2019) (hereinafter *DMF* guidance)[2] and the DMF web page[3] identify the types of DMFs that may be submitted. A Type V DMF is intended for the submission of FDA-accepted reference information and supporting data that are not covered by DMF Types II–IV.

This guidance explains when a Type V DMF may be used to submit information regarding a combination product[4] for which the Center for Drug Evaluation and Research (CDER) has primary jurisdiction[5] (i.e., CDER-led combination product) and which features a device constituent part with electronics and/or software that is planned to be used as a platform, that is, may be used in multiple CDER-led combination products. The guidance also describes the administrative process and outlines the recommended content for these Type V DMF

[1] This guidance has been prepared by the Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research at the Food and Drug Administration in consultation with the Center for Devices and Radiological Health and the Office of Combination Products.

[2] When final, this guidance will represent FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[3] See https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs.

[4] As defined in 21 CFR part 3.

[5] Based on the combination product primary mode of action (PMOA). The PMOA of a combination product is the single mode of action (drug, device, or biological product) expected to make the greatest contribution to the overall intended therapeutic effects of the combination product. See section 503(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act; see also 21 CFR 3.2(k), which defines *mode of action* and *therapeutic*, and (m), which presents a definition for PMOA now codified in section 503(g).

submissions and amendments. Alternatively, applicants may also choose to incorporate by reference device constituent part information available in other submission types, such as a premarket notification submission (510(k)); premarket approval application (PMA); request for classification submitted under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (De Novo request); or device master file (MAF).

This guidance does not address information about device constituent parts that are also container closure systems, which may be submitted as a Type III DMF. For a Type V DMF that is used for a shared system risk evaluation and mitigation strategy (REMS) submission, see draft guidance for industry *Use of a Drug Master File for Shared System REMS Submissions* (November 2017).[6]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Some CDER-led combination products feature a device constituent part with electronics and/or software that may be used as a platform across multiple products. An application for such a combination product may necessitate review[7] by multiple centers, offices, and divisions within FDA.[8] In addition, because the device constituent part may be used as a platform in multiple CDER-led combination products, the same device information may be applicable to and used to support multiple CDER submissions, including an investigational new drug application (IND), a new drug application (NDA), an abbreviated new drug application (ANDA), a biologics license application (BLA), amendments and supplements to these applications, or another DMF. For such combination products, a Type V DMF can be an efficient mechanism to provide information regarding the device constituent part when the same information is applicable to several CDER applications.

Further, because of rapid advances in technology, the device constituent part in these types of combination products could be modified frequently. Knowledge of these modifications is important in determining whether they have any impact on the safety and effectiveness of the

[6] When final, this guidance will represent FDA's current thinking on this topic.

[7] In this guidance, the term *review* also means *assessment*, which is the term that CDER's Office of Pharmaceutical Quality and Office of Generic Drugs will generally use in place of *review*. *Assessment* means the process of both evaluating and analyzing submitted data and information to determine whether the application meets the requirements for approval and documenting that determination.

[8] Cross-center collaboration and/or consultation is important for combination product review. Although CDER is the primary contact for combination products as described in this guidance, CDER consults with other centers as described in FDA's Staff Manual Guide 4101, *Inter-Center Consult Request Process*, available at https://www.fda.gov/media/81927/download.

combination product or its indications for use. As stated in 21 CFR 314.420(c), the DMF holder must submit any change, addition, or deletion of information to the DMF and must notify each person authorized to reference the information. Therefore, an amendment to a Type V DMF may be used to submit information regarding modifications to the device constituent part. Amendments provide a regulatory pathway for the DMF holder to report device modifications and for FDA to review device modifications, including those that may not warrant postapproval reporting by applicants whose applications incorporate the Type V DMF by reference.[9]

A DMF is neither approved nor disapproved. Its technical content is typically reviewed in connection with the review of an IND, NDA, ANDA, or BLA. A DMF is not a substitute for an application (e.g., if the device is also to be marketed alone).

Once FDA reviews the Type V DMF device information for one CDER application, its review may be applicable to other CDER applications if the device information remains unchanged and is pertinent to products in other CDER applications that also incorporate the DMF by reference. FDA's ability to use previously completed scientific reviews for a DMF can contribute to an efficient FDA review process and help ensure consistency across CDER applications referencing the same information.

III. SCOPE

This guidance applies to Type V DMF submissions as described above for CDER-led combination products. Specifically, the information in the guidance may be appropriate for device constituent parts with electronics and/or software that meet the statutory definition of a device and perform functions such as the following:

- Facilitate drug delivery in a manner that may include patient input or analysis (e.g., an electromechanically driven pen injector with software that allows input of patient or dosing information or that analyzes dosing or device use information).

- Provide information that is used in making a decision regarding treatment, therapy, or drug delivery.[10]

- Interface with other devices or systems to provide patient use or other information to the user or health care provider (e.g., physiological parameters).[11]

[9] When a DMF holder amends a DMF, he or she must notify each person (i.e., applicant) authorized to reference the DMF (21 CFR 314.420). It is the responsibility of each applicant to then determine whether a submission to an approved or pending application is necessary.

[10] Section 520(o)(1)(E) of the FD&C Act generally excludes software from the definition of a device if the software supports or provides treatment recommendations to health care professionals and enables them to independently review the basis for the recommendations so that it is not the intent that health care professionals rely primarily on such recommendations.

[11] Section 520(o)(1)(D) of the FD&C Act generally excludes software from the definition of a device if the software is only intended to display or transfer patient data or other medical information.

- Control or drive the features of the user interface.

This guidance addresses process and general content expectations for Type V DMFs for such device constituent parts. It does not address FDA premarket review standards or expectations for such constituent parts or the combination products that include them. This guidance is also not intended to suggest that a Type V DMF should be submitted to CDER if the sponsor has rights of reference to an MAF located in another center containing the same information.

IV. ADMINISTRATIVE PROCEDURES FOR A TYPE V DMF

A. Letter of Intent

As specified in 21 CFR 314.420(a) and noted in the *DMF* guidance, if a prospective DMF holder intends to submit a Type V DMF, he or she must first email a letter of intent to the DMF staff (dmfquestion@cder.fda.gov). The subject field should clearly state "Letter of Intent for Type V DMF."

The letter of intent should include the following information:

- Name, title, address, and contact information for the prospective DMF holder and a contact for FDA correspondence.

- Name of the CDER-led combination product and the name, title, address, and contact information for the combination product applicant.

- Identification and brief description of the device constituent part that is the subject of the DMF.

- Brief description of how the device constituent part in the DMF is used or how it functions in the combination product, if known.

- Purpose and rationale for submitting the Type V DMF, which should explain why the information is not being submitted in an IND, NDA, ANDA, or BLA or amendments and supplements to these applications (e.g., intent to use the device constituent part with more than one drug product, submission of confidential or proprietary information that is not available to the applicant).

If there are any questions, or if additional information is necessary regarding the letter of intent or proposed submission, FDA will contact the prospective DMF holder to discuss and resolve these issues. Once all issues have been resolved or if there are no issues regarding the letter of intent or proposed submission, FDA will provide confirmation to the prospective DMF holder that the Type V DMF may be submitted.

Before submitting a DMF, however, the prospective DMF holder should request a pre-assigned application number. For more information, see Requesting a Pre-Assigned Application Number at https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/requesting-pre-assigned-application-number.

B. Submission

Once FDA provides confirmation that the proposed submission is appropriate for a Type V DMF and a pre-assigned number is obtained, the prospective DMF holder may submit the Type V DMF to CDER.

DMF submissions are subject to the electronic submission requirements as set forth in guidance implementing section 745A of the FD&C Act, including the guidance for industry *Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (Rev. 6, January 2019) (*Providing Regulatory Submissions* guidance).[12] This guidance—*Type V DMFs for CDER-Led Combination Products Using Device Constituent Parts With Electronics or Software*—is not issued under section 745A of the FD&C Act and does not establish legally enforceable responsibilities. To the extent it discusses binding requirements for DMFs, such requirements have been promulgated in previously issued guidance under section 745A and FDA regulations.

Unless otherwise stipulated in the *Providing Regulatory Submissions* guidance or successor guidance under section 745A, paper submissions for Type V DMFs are no longer being accepted.[13] All Type V submissions, whether new DMFs or documents submitted to existing DMFs, must have a DMF number and must be submitted in electronic common technical document (eCTD) format.

For general information and suggestions regarding DMF submissions—including format, content, and process—see the *DMF* guidance. For information about the eCTD format, see the *Providing Regulatory Submissions* guidance and the *eCTD Technical Conformance Guide.*[14] For content recommendations specific to Type V DMFs for combination products as described in this guidance, see sections V–VII.

C. Administrative Review Process

Upon receipt of a DMF, the Central Document Room (CDR) and DMF staff will complete an administrative review. DMF staff will convey any issues or questions identified during the administrative review to the DMF holder, and if there are administrative issues, the submission will be identified as incomplete. Once the administrative issues are adequately addressed, or if there are no administrative issues, FDA will send an acknowledgement letter to the DMF holder listing the DMF number, the subject (title) of the DMF, the DMF holder name, and a statement

[12] Revision 7 of *Providing Regulatory Submissions* is available as a draft guidance. When final, this guidance will represent the FDA's current thinking on this topic.

[13] See *Providing Regulatory Submissions* for information about other DMF types.

[14] See the *eCTD Technical Conformance Guide* at https://www.fda.gov/media/93818/download.

that the submission is a Type V DMF. The submission will then be made available for technical review.

D. Technical Review Process

Before FDA can initiate the technical review of the Type V DMF information in support of an application, the DMF holder should submit a letter of authorization (LOA) to the DMF. The LOA, which can be included in the original or in a subsequent submission, permits FDA to review the Type V DMF and permits authorized parties to incorporate the DMF information into the application. See section V.B.4 for LOA content recommendations.

During the technical review process, the Type V DMF information will be reviewed in conjunction with the authorized application for the combination product. If issues are identified during this review, they will be conveyed to the DMF holder per current procedures for DMF submissions. At the same time, FDA will notify any applicants who have referenced the Type V DMF that additional information is needed.[15] The general subject of the issues will be identified, but the details of the issues will only be disclosed to the DMF holder.

When a DMF holder amends a DMF, he or she must notify each person (i.e., applicant) authorized to reference the DMF (21 CFR 314.420). It is the responsibility of each applicant to then determine whether a submission to an approved or pending application is necessary. An amendment to the Type V DMF used to support an approved NDA, BLA, and ANDA will be reviewed according to current FDA procedures. Generally, this review is triggered by an applicant's submission of an amendment, supplement, or annual report.

If an amendment to a Type V DMF is submitted and no supplement or annual report to an approved application is received, FDA intends to evaluate the changes reported in the DMF amendment to determine whether a supplement to one or more approved applications is needed. If an applicant has determined that a supplement is not necessary and FDA does not agree with that decision (refer to 21 CFR 314.70 and 314.97), FDA will notify the affected applicant.

V. CONTENT RECOMMENDATIONS FOR TYPE V DMF SUBMISSIONS

Type V DMF submissions should contain a cover letter, administrative information, and technical information regarding the device constituent part of the combination product.

[15] For information regarding communications with DMF holders and applicants who reference them, refer to the *DMF* guidance.

A. Cover Letter

The cover letter should clearly state that the submission is an original, FDA-accepted, Type V DMF for a device constituent part of a combination product.[16] In addition to the cover letter content identified in the *DMF* guidance and in the cover letter template on the DMF web page (e.g., DMF information, statement of commitment,[17] DMF holder information), cover letters for Type V DMFs should also include the following information:

- Identification of applications, if known, that the DMF is intended to support, including the name and address of each sponsor, applicant, or holder and all relevant document numbers.

- Identification of the device constituent part and the name of the combination product(s) that uses the device constituent part, if known.

- Statement that a letter of intent was submitted to FDA, the date of that letter, and the date of FDA's response.

B. Administrative Information

The administrative information should include information about the DMF holder and relevant contact information, a reviewer's guide, a copy of the communication from FDA granting permission to submit the Type V DMF, a copy of the LOA provided to the applicant referencing the Type V DMF, and LOAs for any other applications referenced in the Type V DMF submission (if applicable).

1. DMF Holder's Information

DMF holders should include their name and address and the names and addresses of their corporate headquarters, manufacturing/processing facilities, contacts for FDA correspondence, agents (if any), and the title and responsibilities of each person listed in the administrative information.

2. Reviewer's Guide

A reviewer's guide identifies the type and location of information provided in the Type V DMF. This information should be separate from, and referenced after, the cover letter. The reviewer's guide should provide a high-level overview of the submission's content with hyperlinks to the information and should identify the location of the information in the DMF by page number or

[16] FDA is developing a form to replace the cover letter used for most DMF submissions (original and subsequent). The form should be available by the time this guidance is finalized.

[17] Statements of commitment are signed statements from DMF holders certifying that their DMFs are current and that they will comply with the statements made in them. They can be included in the cover letter or separately in the eCTD. See the *DMF* guidance for more information.

section of the eCTD. It should include the general subject areas identified in the "Technical Information" section of this guidance (see section V.C), when applicable, and should clearly identify information that addresses the device constituent part and information that addresses the combination product attributes related to the device constituent part.

3. Communication Granting Permission for Type V DMF Submission

The administrative information should include a copy of the communication from FDA granting permission to submit the Type V DMF.

4. Letter of Authorization

The LOA permits FDA to review the DMF and should include specific information about the DMF and the authorized party as indicated in the LOA template on the DMF web page.

The DMF holder should send a copy of the LOA to the relevant applicants, sponsors, or other holders who are authorized to incorporate by reference the specific information contained in the DMF. The LOA should indicate if the complete DMF or only limited information (identified by submission date, section numbers, and page numbers) may be incorporated by reference. The applicants, sponsors, or other holders referencing the DMF should include a copy of this LOA in their applications for combination products.

5. Reference to Other Applications

If the DMF references information included in another DMF or an application, such as a 510(k), PMA, De Novo request, IND, NDA, ANDA, or BLA, the DMF holder should provide an LOA from that applicant permitting the incorporation of the identified application information into the DMF. The LOA should include the following:

- Date.
- Name of the applicant for the referenced 510(k), PMA, De Novo request, IND, NDA, ANDA, or BLA.
- Application number and supplement or amendment number (if applicable).
- Subject of the application.
- Name of the specific products, items, or information referenced by the LOA. Include the submission date, section numbers, and page numbers.
- Name of people authorized to incorporate information in the application by reference.
- Statement granting authorization to the DMF holder to reference the identified information.

- Name, title, and signature of official authorizing reference to the application.

C. Technical Information

Because the technical information provided in the Type V DMF may need to be reviewed by other centers, offices, or divisions, DMF holders should clearly identify the technical information applicable to the device constituent part only (if applicable) and the combination product attributes related to the device constituent part (if known). The following list identifies some of the general subject areas that may apply:

- Indication for use.
- Device description.
- Software information and documentation.
- Human factors information and testing for the device.
- Sterility assurance.
- Shelf life/Expiration date and testing.
- Biocompatibility information and testing.
- Electrical safety and electromagnetic compatibility testing.
- Bench testing.
- Manufacturing information.[18]

If the technical information references any other premarket submissions, including those reviewed in other centers such as a 510(k), PMA, or De Novo request, the DMF holder should clearly identify the device name, manufacturer, and applicable submission number for the referenced information; the specific information that is being referenced; and the location of this information in the referenced submission. In addition, the technical information should include a scientifically valid explanation regarding how the referenced information is applicable to the Type V DMF submission, the device constituent part, and/or the combination product attributes related to the device constituent part. (See also section V.B.5.)

If the device constituent part is a modification of a previously approved/cleared device or if modifications are made to the device constituent part to allow use with different drug products, the device description information should also include a summary of and the rationale for the modifications.

VI. CONTENT RECOMMENDATIONS FOR TYPE V DMF AMENDMENTS

A Type V DMF amendment may be submitted for changes to the device constituent part (e.g., design or software changes), testing of the device constituent part, or testing of the combination product for attributes related to the device constituent part. When a DMF holder amends a DMF, he or she must also notify the applicants authorized to reference the DMF (21 CFR 314.420).

[18] For additional information regarding manufacturing requirements applicable to combination products, see the guidance for industry and FDA staff *Current Good Manufacturing Practice Requirements for Combination Products* (January 2017).

Applicants are responsible for determining whether submissions to approved or pending applications are necessary.

The Type V DMF amendment should include administrative and technical information as described above, with the provided information focusing on the proposed changes for which the amendment is being submitted.

A. Cover Letter and Administrative Information

The cover letter and administrative section should include the same type of information as described above for the original Type V DMF submission, with the following exceptions:

1. Cover Letter

To help determine the impact of any changes or new information provided in the Type V DMF amendment, the cover letter should briefly describe the change, summarize the analysis and evaluation of the change, and identify the device constituent parts and combination products affected by the change, especially if the Type V DMF is referenced by multiple products. These recommendations are in addition to those identified in the *DMF* guidance and in the cover letter template for subsequent submissions on the DMF web page. The cover letter should also include a confirmation statement that the DMF holder has notified affected applicants of the change to the DMF and the dates of the notifications.

2. Letter of Authorization

If the DMF amendment is referenced in an application, an LOA should be provided in the Type V DMF amendment.

B. Technical Information

The technical information should include the same type of information as described above for the original Type V DMF submission, but should focus on the proposed changes for which the amendment is being submitted. For changes submitted in the amendment, the technical information should include a detailed description of the change, the rationale for the change, and the testing information or supporting documentation for the change.

For new information submitted in the amendment, the technical information should include a detailed description of the new information and the rationale for the submission of this information. In addition, if the new information is replacing information for a Type V DMF submitted previously in a paper copy, the technical information should clearly identify the information that is being replaced, including its location (section and page numbers) and the date of the initial submission. For a Type V DMF submitted in electronic format, the new information should replace the applicable section.

VII. CONTENT RECOMMENDATIONS FOR TYPE V DMF ANNUAL REPORTS

As indicated in the *DMF* guidance, an annual report should be submitted every year to the DMF. This submission should be clearly labeled as an annual report and should include a cover letter, a statement of commitment, DMF administrative information, and the following information:

- A list of any amendments reporting changes and the dates of the amendments submitted since the last annual report, or the original DMF filing date, whichever is most recent, or a statement that no amendments have been submitted since the last annual report or the original filing date, whichever is most recent.

- A complete list of all parties authorized to reference the DMF, the date of the LOA, and the name, reference number, volume, date, and page numbers of the information that each person is authorized to incorporate by reference. The annual report should contain a complete list, even if it is unchanged from the last annual report. If there are no parties authorized to reference the DMF, that should be indicated in the annual report.

- A complete list of all parties for whom authorization to reference the DMF has been withdrawn.

See the subsequent submissions cover letter template and the annual report template, which includes statement of commitment language, on the DMF web page at https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs. Annual reports should not be used to report changes in the DMF; however, DMF holders may submit an annual report at the same time as an amendment containing changes.

VIII. GLOSSARY

The following definitions are for purposes of this guidance only:

Agent: A legal entity, whether a company or an individual, that is not employed by but is authorized to act on behalf of a DMF holder.

Applicant: Any person who submits an application to obtain FDA approval or license to market a drug or biologic.

Authorized party: Any person who is authorized to reference a DMF.

Combination product: A product composed of any combination of a drug and device, a biological product and a device, a drug and a biological product, or a drug, device, and a biological product, as defined in 21 CFR 3.2(e).

Constituent part: A drug, device, or biological product that is part of a combination product (21 CFR 4.2).

Contact person: An employee of the DMF holder or agent to whom communication from FDA should be sent. The contact person may or may not be the same individual as the responsible official.

DMF holder: A person who owns a DMF.

Letter of authorization: A letter from a DMF holder that authorizes an applicant or another DMF holder to incorporate by reference all or part of the DMF's contents to support an application, supplement, or another DMF or an amendment to any of these documents. The LOA also authorizes FDA to review applicable portions of the DMF.

Person: An individual, partnership, corporation, or association (section 201(e) of the FD&C Act).

Responsible official: The employee of the DMF holder or agent who is responsible for submitting information to the DMF.

Right of reference: The authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval for an application, including the ability to make available the underlying raw data from the investigation for FDA audit, if necessary (21 CFR 314.3(b)).

Sponsor: A person or agency who assumes responsibility for an investigation of a CDER-led combination product, including responsibility for compliance with applicable provisions of the act and regulations. The sponsor may be an individual, pharmaceutical or device company, governmental agency, academic institution, private organization, or other organization.