https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs?utm_medium=email&utm_source=govdelivery

Drug Master Files (DMFs)

What's New

GDUFA III enhancements for Type II API DMFs start on 10/1/2022

- Visit GDUFA III Drug Master File (DMF) Review Enhancements (/industry/generic-drug-user-fee-amendments/gdufa-iii-drug-master-file-dmf-review-enhancements) for more information
- Send questions to DMFOGD@fda.hhs.gov (mailto:DMFOGD@fda.hhs.gov)
- Draft Guidance for Industry: Review of Drug Master Files in Advance of Certain ANDA Submissions Under GDUFA (/regulatory-information/search-fda-guidance-documents/review-drug-master-files-advance-certain-anda-submissions-under-gdufa)
- SBIA DMF Workshop: *GDUFA III Enhancements and Structured Data Submissions* coming November 30, 2022 – **Sign Up Now! (https://www.fda.gov/news-events/drug-master-file-dmf-workshop-gdufa-iii-enhancements-and-structured-data-submissions-11302022)**

Drug master files (DMFs) are submissions to FDA used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products. They:

- Allow parties to reference material without disclosing DMF contents to those parties.
- Are not required by statute or regulation.
- Are neither approved nor disapproved. Instead, FDA reviews the technical contents of DMFs in connection with the review of applications that reference them (e.g., NDAs, ANDAs, INDs, BLAs).

See the draft guidance for industry Drug Master Files (/regulatory-information/search-fda-guidance-documents/drug-master-files-guidance-industry) for detailed information about preparing and submitting DMFs and to learn about FDA's DMF review process. (When final, this guidance will represent FDA's current thinking on DMFs.)

The following DMF web pages cover additional information about DMFs and their

submission:

- List of DMFs (/drugs/drug-master-files-dmfs/list-drug-master-files-dmfs)
- Types of DMFs (/drugs/drug-master-files-dmfs/types-drug-master-files-dmfs)
- Submission Resources (/drugs/drug-master-files-dmfs/drug-master-file-dmf-submission-resources)
- Templates (/drugs/drug-master-files-dmfs/drug-master-file-dmf-templates)
- Related Information (/drugs/drug-master-files-dmfs/drug-master-file-dmf-related-information)
- Frequently Asked Questions (FAQs) *(coming soon)*

Contact Information

Please contact dmfquestion@fda.hhs.gov (mailto:dmfquestion@fda.hhs.gov) with all DMF-related submission questions. Include the DMF number, if applicable.

Physical Media Submissions (only accepted if submission is over 10 gigabytes):

CDER
Food and Drug Administration Center for Drug Evaluation and Research Central Document Room 5901-B Ammendale Road Drug Master File Staff Beltsville, MD 20705-1266

CBER
Document Control Center 10903 New Hampshire Avenue Building 71, Room G112 Silver Spring, MD 20993-0002