From: OC GCP Questions
To: [redacted]
Subject: RE: eTMF guidance
Date: Monday, January 28, 2019 2:33:00 PM
Attachments: [redacted]

Dear [redacted],
Master files are the responsibility of each of the Centers (CDER< CBER, and CDRH). I can give you general informa ion on master files for each of the three Centers, which can be found on FDA's website. If you have specific questions about a master file, please contact the appropriate Center (CDER, CBER, or CDRH) for more information. Contact information for each Center is included at the bottom of their section.

CDRH:
https://www.fda gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm142714.htm

The Content of an MAF
There are no specific content requirements for a MAF. However, a submission will not be accepted as an MAF if it is not substantive in nature and does not contain information that may reasonably be regarded as trade secret or confidential commercial or financial information.
The submission must include a cover letter, preferably bearing company letterhead, signed by a responsible official (e g., Director of Regulatory Affairs or another manager). The letter should identify the submission as an MAF, and a contact person at the company or designated agent should be listed.
An MAF must be in the English language or be accompanied by accurate English translations of any of the documents that are in a language other than English.

Procedural and other questions regarding MAFs should be directed to: Wanda sawyer-major@fda hhs gov or 301-796-6568

CBER: https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/NewDrugApplicationNDAProcess/ucm211604.htm

FDA ordinarily neither independently reviews DMFs nor approves or disapproves submissions to a DMF Instead, we customarily review the information in a DMF only in the context of an application, e g , when a sponsor or applicant references material in a DMF within their application or supplement

What address should be used to send Drug Master Files to CBER?

Drug Master Files and Updates (when changes occur that might impact products) to Drug Master Files for CBER-regulated products should be sent to:

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

To submit electronically, please refer to the guidance entitled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications; Guidance for Industry" which can be found at
https://www fda gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm333969 pdf

Consumer Affairs Branch (CBER) (800) 835-4709 (240) 402-8010 ocod@fda hhs gov

Division of Communication and Consumer Affairs
Office of Communication, Outreach and Development
Food and Drug Administration
10903 New Hampshire Avenue
Building 71 Room 3103
Silver Spring, MD 20993-0002

CDER: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default htm

A Drug Master File (DMF) is a submission to the Food and Drug Administration (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

Beginning on May 5, 2018, new DMFs, as well as all documents submitted to existing DMFs, must be submitted using the Electronic Common Technical Document (eCTD) DMF submissions that are not submitted in eCTD format after this date will be rejected

Please contact dmfquestion@cder.fda.gov with all DMF-related submission questions. Please include the DMF number, if applicable.

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst

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Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration
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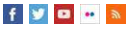

judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Friday, January 04, 2019 12:34 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: eTMF guidance

Good Morning,

Is it acceptable for a sponsor/CRO of a drug, biologic, or device study to maintain all TMF records electronically (eTMF)? My understanding is this is acceptable, however, is there any guidance on documents contained within the eTMF being a "certified copy" of the original vs simply an electronic copy? Are there any expectations for any TMF documents being retained as originals "wet ink"?

Thank you!

[redacted]