

# SBIA-DMF Drug Substance Workshop

March 3 & 4, 2021 (Virtual)

FDA

## Introduction to FDA Drug Master File Form 3938

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## PURPOSE

Here we describe a new FDA form (Form 3938) for use with all types of DMF submissions.

### Form 3938:

1. Provides a standardized fillable electronic form for Drug Master File (DMF) submissions similar to the 356h Form currently used for application submissions.
2. Allows for automated pull of DMF information into FDA databases
3. Captures relevant DMF submission information submitted using eCTD format.
4. Will enhance the accuracy and efficiency in processing DMF submissions

## OBJECTIVE(S)

1. Understand when to use Form 3938.
2. Understand who should use Form 3938.
3. Learn how to properly fill out basic information, holder information, submission classifications, and facility information.
4. Get answers to some frequently asked questions about Form 3938.

## METHOD(S)

This presentation has 3 parts:

1. Introduction to Form 3938
2. Walkthrough of the entire Form to illustrate the function of all sections and fields.
3. Frequently Asked Questions

Go to this link to view a recorded webinar on Form 3938: (final link here when available)

## RESULT(S)

When should and how should I use Form 3938?

- When it becomes official Form 3938 should accompany all DMF submissions submitted in eCTD format.
- In many cases the form can replace the cover letter that is currently used.
- The form is designed to accurately capture the type and category of a DMF submission through the use of checkboxes so it is properly processed by FDA.
- “Smart” features of the form ensure it is filled out correctly.
- The form captures facility information so an accurate facility profile for the DMF is readily available.

Basic Information:

1. Date of Submission (mm/dd/yyyy)	2. DMF Number
12/20/2020	123456
3. DMF Subject (Title)	
Madeupthricin	
4. DMF Type (Select one)	
<input checked="" type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V	

Submission Type/Category Information:

7. Submission Type (May select more than one)		
<input type="checkbox"/> Original (New)	<input type="checkbox"/> Withdrawal of Letter of Authorization	<input type="checkbox"/> Response to Deficiency, Complete Response, Information Request or Additional Comments Letter
<input type="checkbox"/> Administrative Amendment	<input type="checkbox"/> Meeting	<input type="checkbox"/> REMS - Risk Evaluation and Mitigation Strategy
<input type="checkbox"/> Annual Report	<input checked="" type="checkbox"/> Quality Amendment	<input type="checkbox"/> Other (Specify):
<input type="checkbox"/> Letter of Authorization	<input type="checkbox"/> Response to Administrative Filing Issue	
8. Amendment Type, if applicable (May select more than one)		
<input type="checkbox"/> Change of agent/address/contact person	<input type="checkbox"/> Manufacture Information	<input type="checkbox"/> REMS Modification-Due to Safety Labeling Changes
<input type="checkbox"/> Change of holder/address/contact person	<input type="checkbox"/> Microbiology Information	
<input type="checkbox"/> Change of DMF Subject (title)	<input type="checkbox"/> New Item	<input type="checkbox"/> REMS Modification-Major
<input type="checkbox"/> Change of DMF Type	<input type="checkbox"/> Packaging Information	<input type="checkbox"/> REMS Modification-Minor
<input type="checkbox"/> Meeting Package	<input checked="" type="checkbox"/> Stability Information	<input type="checkbox"/> REMS Proposal-Standard
<input type="checkbox"/> Meeting Request	<input type="checkbox"/> REMS Final	<input type="checkbox"/> REMS Correspondence
<input checked="" type="checkbox"/> Controls Information	<input type="checkbox"/> REMS Assessment	<input type="checkbox"/> Agent Appointment
<input type="checkbox"/> Facility Information	<input type="checkbox"/> REMS Assessment Methodology	<input type="checkbox"/> Other (Specify):
<input type="checkbox"/> Formulation Information	<input type="checkbox"/> REMS Revision	

## CONCLUSION(S)

Should I still provide a cover letter with my submissions?

For many simple or administrative submissions such as an Annual Report or an LoA the form may take the place of the cover letter. For more complicated or technical submissions the cover letter and/or summary of changes should still be provided as an aid to the review staff.

Can a DMF Agent sign DMF Form 3938?

Yes, either the Responsible Official at the DMF Holder company or the Appointed Agent can sign DMF Form 3938.

When will Form 3938 be available for use?

The form is currently in the approval process at FDA and Office of Management and Budget (OMB). We hope to have the form available for general use with DMF submissions sometime in 2021

Please stay tuned! More information will be released on the form and instructions prior to launch.

## WHERE TO GET MORE INFORMATION & LINKS.

Send questions regarding this poster to: [DMFOGD@FDA.HHS.GOV](mailto:DMFOGD@FDA.HHS.GOV) by 2/15/2021 for inclusion in the poster Q&A session on March 3<sup>rd</sup>.

FDA DMF Website:

<https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs>

Pre-assigned DMF Number Request:

<https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/requesting-pre-assigned-application-number>

- To view the full webinar on DMF Form 3938 please use the YouTube link shown below which is also provided on the Workshop poster page.
  - Link: <https://youtu.be/OyHk9G4omOo>
- The webinar is approximately 29 minutes long.

# Thank You!

- Send questions regarding this poster to: [DMFWorkshop2021@fda.hhs.gov](mailto:DMFWorkshop2021@fda.hhs.gov) by 2/15/2021 for inclusion in the poster Q&A session on *March 3<sup>rd</sup>*.
- Follow-on webinar for both posters/presentations is on April 9, 2021. Questions can be sent to the above email by 3/19/2021 for the webinar.
- Please refer to the following presentations on March 3<sup>rd</sup> and 4<sup>th</sup> for additional information:

Administrative Aspects of Managing a DMF by Vathsala Selvam

Managing Electronic DMF Submissions by Jonathan Resnick