

FDA Form 3938 Drug Master File (DMF)

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On behalf of
Division of Regulations, Guidance, and Standards
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Part I

- Acronyms
- Definitions
- Purpose of Form 3938
- When should Form 3938 be used?
- Who should use Form 3938?

Part II

• **LIVE** walk-through of form 3938

Part III

FAQs

Acronyms



DMF – Drug Master File

ESG – Electronic Submission Gateway

eCTD – Electronic Common Technical Document

LoA – Letter of Authorization

REMS – Risk Evaluation and Mitigation Strategy

Definitions



Type II DMF:

DMF related to Drug Substance, Drug Substance Intermediate, and Materials Used in Their Preparation, or Drug Product

Type III DMF:

DMF related to Packaging Material

Type IV DMF:

DMF related to Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation

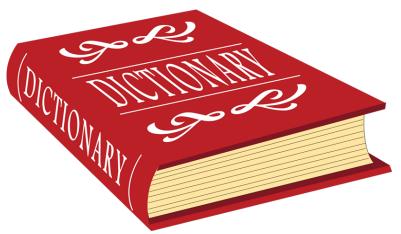
Type V DMF:

DMF related to FDA-Accepted Reference Information (includes REMS)



Responsible Official

The Responsible Official is an employee at a company who has signatory authority to sign company documents.





Purpose of DMF Form 3938



Provide a standardized fillable electronic form for Drug Master File (DMF) submissions

Allow for automated pull of DMF information into FDA databases

Capture relevant DMF submission information submitted using the electronic Common Technical Document (eCTD) format.

When Should Form 3938 be Used?





- Form 3938 should accompany all DMF submissions submitted in eCTD format.
- Note: Type III DMF is exempt from the eCTD requirement. It can be submitted in eCTD or non-eCTD format through ESG. It can also be submitted in non-eCTD through CDER NextGen Portal.

Who Should Use Form 3938?



The DMF Holder

• The U.S. Agent

A 3rd Party Contractor

When will the form be available form 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!



WALK-THROUGH OF FORM 3938 WITH MOCK DATA

DMF Information Fields 1 to 4



1. Date of Submission (mm.	/dd/yyyy)				2. DMF Number	
12/20/2020					123456	
3. DMF Subject (Title)						
Madeupthricin						
4. DMF Type (Select one)	X II	III	□ IV	V		





5. Holder Information	
Holder Name	Holder DUNS Number
Magic Kingdom, Inc.	984123654
Holder Address	
Address 1 (Street address, P.O. box, etc.)	
1000 Fun Street	
Address 2 (Apartment, suite, unit, building, floor, etc.)	
City	State/Province/Region
Orlando	Florida
Country	ZIP or Postal Code
USA	32801
Holder Contact (Name of person)	Holder Contact Telephone Number (Include country code, if applicable, and area code)
Goofy Dawg	(111) 987-6543
Holder Contact Email Address	Holder Contact FAX Number (Include country code, if applicable, and area code)
goofydaug@magic.net	(111) 987-5432





6. DMF Agent (Recommended for DMFs submitted by non-U.S. con	npanies)
DMF Agent Name	
ABC Company LLC	
Agent Address	
Address 1 (Street address, P.O. box, etc.) 2222 Epcot Way	
Address 2 (Apartment, suite, unit, building, floor, etc.)	
City	State/Province/Region
Laurel	Virginia
Country	ZIP or Postal Code
USA	22046
Agent Contact (Name of person)	Agent Contact Telephone Number (Include country code, if applicable, and area code)
Mr. John Smith	222-123-4567
Agent Contact Email Address	Agent Contact FAX Number (Include country code, if applicable, and area code)
JSmith@abccompany.com	Not Available

DMF Information Field 7 (Scenario 1 & 2)



Scenario 1

Section 1		
7. Submission Type (May select more	than one)	
Original (New)	Withdrawal of Letter of Authorization	Response to Deficiency, Complete Response,
Administrative Amendment	Meeting	Information Request or Additional Comments Letter
Annual Report	Quality Amendment	REMS - Risk Evaluation and Mitigation Strategy
∠ Letter of Authorization	Response to Administrative Filing Issue	Other (Specify):
Scenario 2		
7. Submission Type (May select more	than one)	
Original (New)	Withdrawal of Letter of Authorization	Response to Deficiency, Complete Response, Information Request or Additional Comments
Administrative Amendment	Meeting	Letter
Annual Report	Quality Amendment	REMS - Risk Evaluation and Mitigation Strategy
Letter of Authorization	Response to Administrative Filing Issue	Other (Specify):

DMF Information Fields 8 (Scenario 1)



7. Submission Type (May select more	than one)			
Original (New)	Withdrawal	of Letter of Authorization		Response to Deficiency, Complete Response,
Administrative Amendment	Meeting			nformation Request or Additional Comments etter
Annual Report	Quality Ame	endment	R	REMS - Risk Evaluation and Mitigation Strategy
Letter of Authorization	Response to Issue	o Administrative Filing	C	Other (Specify):
8. Amendment Type, if applicable (May	select more than	n one)		
Change of agent/address/conta	ct person	Manufacture Information	1	REMS Modification-Due to Safety
Change of holder/address/conta	act person	Microbiology Information	1	Labeling Changes
Change of DMF Subject (title)		New Item		REMS Modification-Major
Change of DMF Type		Packaging Information		REMS Modification-Minor
Meeting Package		Stability Information		REMS Proposal-Standard
		REMS Final		REMS Correspondence
Controls Information		REMS Assessment		Agent Appointment
Facility Information		REMS Assessment Met	hodolo	ogy Other (Specify):
Formulation Information		REMS Revision		

DMF Information Fields 8 (Scenario 2)



7. Submission Type (May select more	than one)			
Original (New)	Withdrawal	of Letter of Authorization		Response to Deficiency, Complete Response,
Administrative Amendment	Meeting			Information Request or Additional Comments Letter
Annual Report	Quality Ame	endment		REMS - Risk Evaluation and Mitigation Strategy
Letter of Authorization		o Administrative Filing		Other (Specify):
	Issue			
8. Amendment Type, if applicable (May	select more than	one)		
Change of agent/address/conta	ct person	Manufacture Information	1	REMS Modification-Due to Safety
Change of holder/address/conta	act person	Microbiology Information	n	Labeling Changes
Change of DMF Subject (title)		New Item		REMS Modification-Major
Change of DMF Type		Packaging Information		REMS Modification-Minor
Meeting Package		Stability Information		REMS Proposal-Standard
		REMS Final		REMS Correspondence
Controls Information		REMS Assessment		Agent Appointment
Facility Information		REMS Assessment Met	hodo	ology Other (Specify):
Formulation Information		REMS Revision		

DMF Information Fields 8 (Scenario 3)



7. Submission Type (May select more t	han one)			
Original (New)	Withdrawal of	Letter of Authorization		Response to Deficiency, Complete Response,
Administrative Amendment	Meeting			Information Request or Additional Comments Letter
Annual Report	Quality Amend	dment		REMS - Risk Evaluation and Mitigation Strategy
Letter of Authorization	Response to A	Administrative Filing		Other (Specify):
	Issue			
8. Amendment Type, if applicable (May	select more than o	ne)		
Change of agent/address/contact	ct person	Manufacture Information	n	REMS Modification-Due to Safety
Change of holder/address/conta	ct person	Microbiology Informatio	n	Labeling Changes
Change of DMF Subject (title)		New Item		REMS Modification-Major
Change of DMF Type		Packaging Information		REMS Modification-Minor
Meeting Package		Stability Information		REMS Proposal-Standard
☐ Meeting Request		REMS Final		REMS Correspondence
		REMS Assessment		Agent Appointment
Facility Information		REMS Assessment Me	thodo	logy Other (Specify):
Formulation Information		REMS Revision		

DMF Information Fields 8 (Scenario 4)



7. Submission Type (May select more	than one)			
Original (New)	Withdrawal of L	etter of Authorization		sponse to Deficiency, Complete Response,
Administrative Amendment	Meeting		Let	ormation Request or Additional Comments tter
Annual Report	Quality Amendr	nent	RE	MS - Risk Evaluation and Mitigation Strategy
Letter of Authorization	Response to Ac	Iministrative Filing	Oth	ner (Specify):
8. Amendment Type, if applicable <i>(May</i>	select more than one	e)		
Change of agent/address/conta	ct person	Manufacture Information	1	REMS Modification-Due to Safety
Change of holder/address/conta	act person	Microbiology Information	า	Labeling Changes
Change of DMF Subject (title)		New Item		REMS Modification-Major
Change of DMF Type	\boxtimes	Packaging Information		REMS Modification-Minor
Meeting Package		Stability Information		REMS Proposal-Standard
		REMS Final		REMS Correspondence
Controls Information		REMS Assessment		Agent Appointment
Facility Information		REMS Assessment Met	hodolog	y Other (Specify):
Formulation Information		REMS Revision		

DMF Information Field 9



9. Establishment Information (Full establishment information should be provided in the body of the DMF. Refer to the instruction sheet for more information. To add additional establishment(s), press button at bottom of section; this may be repeated as needed.) **Establishment Name** Health Path, Inc. **Establishment Address** Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit, building, floor, etc.) State/Province/Region City Buckystown California ZIP or Postal Code Country USA 20814 Establishment DUNS Number Registration (FEI) Number 9876543210 123456789 Is the establishment new to the DMF? ⋈ No Yes Establishment Role (e.g. manufacturing step, type of testing) Manufacturing Is the establishment ready for inspection? (See instructions) If not, when will site be ready? (See instructions) 10/25/2021 Yes ⋈ No Establishment Contact (Name of person) Establishment Contact Telephone Number (Include country code, if applicable, and area code) Ms. Jane Doe 301-234-8758 Establishment Contact Email Address Establishment Contact FAX Number (Include country code, if applicable, and area code) JaneDoe@healthpath.com 301-234-8700 Click this button to add entries for an additional establishment. May be repeated as needed. Add Establishment **Delete Page** Click this button to delete page. May be repeated as needed.

DMF Information Field 10



10. Cross-Referenced DMF(s)

DMF Number 009876 / Subject: Cough Medicine / Holder: XY Pharmaceutical, Inc.





CERTIFICATION

I agree to update this Drug Master File as required in 21 CFR 314.420(c) and notify in writing each person authorized to reference that information. I agree to comply with all applicable laws and regulations that apply to Drug Master Files.

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be current, true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Typed Name and Title	of Responsible Official		12. Date (mm/dd/yyyy)
John Smith, Manager of R	egulatory Affaris		12/20/2020
13. Telephone Number		14. FAX Number (Include	
(Include country code, if		country code, if applicable,	not available
applicable, and area code)		and area code)	
15. Email Address			

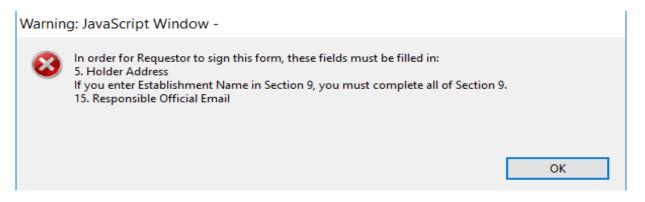
JSmith@abecompany.com

DMF Information Fields 16 & 17



16	Address of Person Named in Item 11			
	Address 1 (Street address or P.O. box, company name)			
	ABC Company LLC			
	Address 2 (Apartment, suite, unit, building, floor, etc.)			
	2222 Epcot Way			
	City	State/Province	e/Region	
	Laurel	Virginia		
	Country		ZIP or Postal Code	
	USA		22046	
17	. Signature of Person Named in Item 11	gn		
MAN AND AND AND AND AND AND AND AND AND A				

Example of Pop-Up Window



DMF Information End of FDA DMF Form 3938



This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



Question Can a contracted company sign DMF Form

3938?

Answer No. A third party (contracted company)

cannot sign DMF Form 3938.





<u>Question</u>

Can a DMF Agent sign DMF Form 3938?

<u>Answer</u>

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





Question

When another employee signs on behalf of the Responsible Official with a digital signature, does the Responsible Official's name still need to be identified on the signed form?

<u>Answer</u>

It is acceptable for another employee to sign on behalf a company's Responsible Official as long as the signed form reflects the Responsible Official's name in Field 11.

John Hancock.



Question

Should a FAX number be entered on Form 3938 for each relevant section?

Answer

A FAX number should be entered on Form 3938 if available. If no FAX number is available then enter "not available" in the appropriate field of DMF Form 3938.

If either a FAX number or "not available" is not inserted in the relevant section you will receive an error message.



Question Must a pre-assigned DMF number be

obtained in advance of submitting an original

DMF in eCTD format?

Answer Yes. For more information see Requesting a

Pre-Assigned DMF Number at:

https://www.fda.gov/drugs/electronic-regulatorysubmission-and-review/requesting-pre-assignedapplication-number



Question

Must a DMF holder contact FDA before applying for a pre-assigned DMF number for a Type V DMF?

Answer

For Sterile Processing Facilities the DMF holder need not submit a letter of intent but should specify in the pre-assigned DMF number request and in the original submission's Cover Letter that the DMF is for a Sterile Processing Facility.

For all other Type V submissions, the DMF holder must first submit a letter of intent to the Agency. The Agency will then contact the DMF Holder to discuss the proposed submission.



Question What should be included in a letter of intent

for a Type V DMF?

Answer

DMF holders should send their requests to dmfquestion@fda.hhs.gov with the following information:

- An explanation of the necessity for filing the information in a Type V DMF
- If REMS, indicate the request is for a REMS DMF
- The proposed Subject (Title) of the DMF
- The rationale for not submitting the information in an application
- The clinical division that will be reviewing the information, if applicable



<u>Question</u> How are FEI numbers obtained for facilities that

do not have an FEI number?

Answer FEI numbers can be obtained by sending a

request to;

FDAGDUFAFEIRequest@fda.hhs.gov

FDA

FAQs - Form 3938

Question

Must I obtain a pre-assigned DMF number when I convert a paper DMF to eCTD Format?

<u>Answer</u>



No. There is no need to request a new DMF number when converting from paper to eCTD. You should continue to use the same DMF number

Note: If the existing DMF number is not 6 digits, prepend the number "0" to make it 6 digits (e.g. 001234)



<u>Question</u> Answer

Can a DMF be held by multiple entities?

No. Only one person/entity can be the holder of a DMF.





Question

How does the Agency define the DMF Holder?

<u>Answer</u>

The DMF Holder is a person who owns a DMF. According to section 201(e) of the Federal Food, Drug, and Cosmetic Act, the term 'person' includes individual, partnership, corporation, and association.



Question

Is a DMF Holder required to appoint a

U.S. Agent?

<u>Answer</u>

Although there is no regulation that requires DMF Holders to appoint an Agent, the Agency strongly recommends appointment of a U.S. Agent for companies outside of the U.S.



Question

Should DMF holder be the manufacturer of the Subject of the DMF?

<u>Answer</u>

If the DMF holder is not the manufacturer, the DMF holder should include a signed statement in their original submission that the DMF holder assumes full responsibility for the manufacturing of the Subject of the DMF.



Establishment Contact?



Question

If the person identified as the Establishment Contact for a facility changes, is it necessary to submit a Form 3938 with a revised

Answer

Yes. An amendment should be submitted to the DMF notifying the Agency of any changes to previously submitted information.



Question

What should I enter if I do not yet have an FEI number or a DUNS number?

<u>Answer</u>

The form does require an entry in these fields to avoid an error. If an FEI/DUNS is not available just enter "999999999" (10 digits) in an FEI field or "99999999" (9 digits) in a DUNS field. This will allow the form to be finalized.



<u>Question</u>

Should I still provide a cover letter with my submissions?

<u>Answer</u>

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.



Question

I am removing a facility in this amendment, should I include it in the form?

<u>Answer</u>

No. The form should list only the current facilities associated with the DMF. Note the facility being removed in the cover letter, Summary of Changes, and 3.2.S.2.1.

Resources



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

eCTD Website:

https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd

DMF Questions:

dmfquestion@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HU Food and Drug Administr Drug Master F	ation	Form Approved: OMB No. xxxx-xxx Expiration Date: Xxxxxxxxxx, 201x See PRA Statement on last page.
Date of Submission (mm/dd/yyyy)	12 DM	F Number
12/20/2020	12345	
3. DMF Subject (Title)		
Madeupthricin		
4. DMF Type (Select one)	□v	
5. Holder Information		
Holder Name	H	older DUNS Number
Magic Kingdom, Inc.	9	84123654
Holder Address	'	
Address 1 (Street address, P.O. box, etc.)		
1000 Fun Street		
Address 2 (Apartment, suite, unit, building, floor, etc.)		
City	State/	Province/Region
Orlando	Florid	
Country		ZIP or Postal Code
USA		32801
Holder Contact (Name of person)		older Contact Telephone Number (Include country code, pplicable, and area code)
Goofy Dawg	(111) 987-6543
Holder Contact Email Address		older Contact FAX Number (Include country code, if pplicable, and area code)
goofydaug@magic.net		111) 987-5432
8. DMF Agent (Recommended for DMFs submitted by non	-U.S. companies	
DMF Agent Name		
ABC Company LLC		
Agent Address		
Address 1 (Street address, P.O. box, etc.) 2222 Epcot Way		
Address 2 (Apartment, suite, unit, building, floor, etc.)		
City	Ctotol	Province/Region
Laurel	Virgin	
Country	- 22 gan	ZIP or Postal Code
USA		22046
Agent Contact (Name of person)		gent Contact Telephone Number (Include country code, i pplicable, and area code)
Mr. John Smith		22-123-4567
Agent Contact Email Address		gent Contact FAX Number (Include country code, if pplicable, and area code)
JSmith@abecompany.com		lot Available

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Original (New)	Withdraw	al of Lette	er of Authorization			ncy, Complete Response
Administrative Amendment	Meeting			Inforr Lette		or Additional Comments
Annual Report	Quality Ar	mendmen	t			tion and Mitigation Strate
Letter of Authorization	_		nistrative Filing		r (Specify):	ū
	Issue				(ореспу).	
Amendment Type, if applicable (M	ay select more th	an one)				
Change of agent/address/cor	tact person	M	lanufacture Informati	ion	☐ REMS Mod	dification-Due to Safety
Change of holder/address/co	ntact person		icrobiology Informat	ion	Labeling C	hanges
Change of DMF Subject (title	-		ew Item		☐ REMS Mod	dification-Major
Change of DMF Type	•	⊠ p	ackaging Information	n	=	dification-Minor
Meeting Package			tability Information		☐ REMS Pro	posal-Standard
Meeting Request			EMS Final		=	respondence
Controls Information			EMS Assessment		Agent App	•
Facility Information			EMS Assessment M	lethodology		
Formulation Information			EMS Revision			,,.
Health Path, Inc. Establishment Address Address 1 (Street address)				or occurry, in		,
Establishment Name Health Path, Inc. Establishment Address	t, building, floor, e	stc.)				,
Establishment Name Health Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit	i, building, floor, e	itc.)	State/Provinc			,
Establishment Name Health Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit City Buckystown	i, building, floor, e	etc.)		e/Region		,
Establishment Name Health Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit City Buckystown Country	t, building, floor, e	etc.)	State/Provinc	e/Region		,
Establishment Name Health Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit City Buckystown Country USA	t, building, floor, e	etc.)	State/Provinc California	ziP or Pos 20814	tal Code	
Establishment Name Health Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit City Buckystown Country USA Establishment DUNS Number	i, building, floor, e	tc.)	State/Provinc	ziP or Pos 20814	tal Code	
Establishment Name Health Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit City Buckystown Country USA Establishment DUNS Number 123456789		etc.)	State/Provinc California	ziP or Pos 20814	tal Code	
Establishment Name Health Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit City Buckystown Country		etc.)	State/Provinc California	ziP or Pos 20814	tal Code	
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Establishment Name Health Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit City Buckystown Country USA Establishment DUNS Number 123456789 Is the establishment new to the DMF			State/Provinc California	ziP or Pos 20814	tal Code	
Establishment Name Health Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit City Buckystown Country USA Establishment DUNS Number 123456789 Is the establishment new to the DMF Yes No Establishment Role (e.g. manufactur Manufacturing	ring step, type of t	testing)	State/Provinc California	ziP or Pos 20814	tal Code	
Establishment Name Health Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit City Buckystown Country USA Establishment DUNS Number 123456789 Is the establishment new to the DMF Yes No Establishment Role (e.g. manufactur Manufacturing	ring step, type of l otion? (See instru	testing)	State/Provinc California	ze/Region ZIP or Pos 20814 FEI) Numbe	tal Code	
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Establishment Name [ealth Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit City Buckystown Country USA Establishment DUNS Number 123456789 Is the establishment new to the DMF Yes No Establishment Role (e.g. manufactur Manufacturing Is the establishment ready for inspecting the stablishment contact (Name of per	ring step, type of i stion? (See instru If not, when w	testing)	State/Provinc California Registration (9876543210 ready? (See instruct Establish	ziP or Pos 20814 FEI) Numbe	tal Code r	
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Establishment Name Health Path, Inc. Establishment Address Address 1 (Street address) 3333 Main Street Address 2 (Apartment, suite, unit City Buckystown Country USA Establishment DUNS Number 123456789 Is the establishment new to the DMF Yes No Establishment Role (e.g. manufactur Manufacturing Is the establishment ready for inspect	ring step, type of to otion? (See instruc If not, when w	testing)	State/Provinc California Registration (9876543210 ready? (See instruction ode, if a 301-234 Establist Establist (1001-214 (1001	zi/Region ZIP or Pos 20814 FEI) Numbe stions) 10/25 ment Conta applicable, a 8758 ment Conta le, and area	tal Code r /2021 ct Telephone Nind area code)	umber (Include country
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Completed Form (Page 3)



DMF Number 009876 / Subject: Cough Medicine / Holder: XY Pharmaceutical, Inc. EERTIFICATION agree to update this Drug Master File as required in 21 CFR 314.420(c) and notify in writing each person authorized to reference that normation. I agree to comply with all applicable laws and regulations that apply to Drug Master Files. The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be current, true and socurale. Naming: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001. 11. Typed Name and Title of Responsible Official folial foli	10. Cross-Referenced DMF(s)				
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