FDA Form 3938
Drug Master File (DMF)

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On behalf of
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Office of Policy for Pharmaceutical Quality
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- **Part I**
  - Acronyms
  - Definitions
  - Purpose of Form 3938
  - When should Form 3938 be used?
  - Who should use Form 3938?
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- **Part III**
  - FAQs

Acronyms

DMF – Drug Master File

ESG – Electronic Submission Gateway

eCTD – Electronic Common Technical Document

LoA – Letter of Authorization

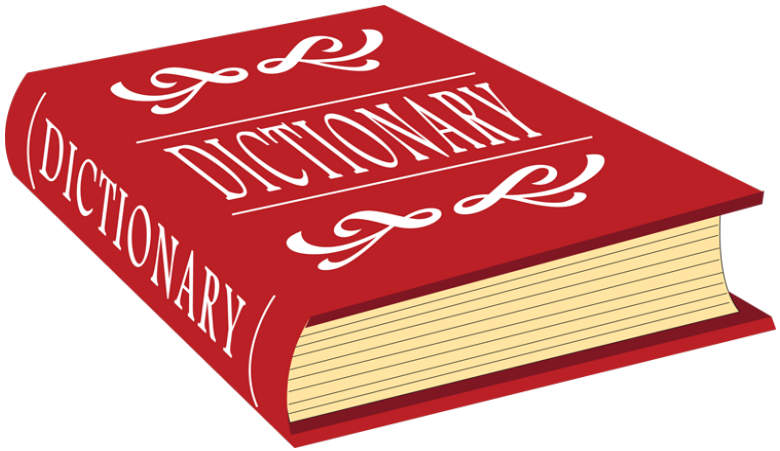
REMS – Risk Evaluation and Mitigation Strategy

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 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!

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)* ☒ II ☐ III ☐ IV ☐ V	

DMF Information
Field 5

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

DMF Information
Field 6

6. 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	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

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 Letter
☐ Administrative Amendment	☐ Meeting	
☐ 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 Letter
☒ Administrative Amendment	☐ Meeting	
☐ 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)*

- [x] Original (New)
- [ ] Administrative Amendment
- [ ] Annual Report
- [ ] Letter of Authorization
- [ ] Withdrawal of Letter of Authorization
- [ ] Meeting
- [ ] Quality Amendment
- [ ] Response to Administrative Filing Issue
- [ ] Response to Deficiency, Complete Response, Information Request or Additional Comments Letter
- [ ] REMS - Risk Evaluation and Mitigation Strategy
- [ ] Other *(Specify)*:

8. Amendment Type, if applicable *(May select more than one)*

- [ ] Change of agent/address/contact person
- [ ] Change of holder/address/contact person
- [ ] Change of DMF Subject (title)
- [ ] Change of DMF Type
- [ ] Meeting Package
- [ ] Meeting Request
- [ ] Controls Information
- [ ] Facility Information
- [ ] Formulation Information
- [ ] Manufacture Information
- [ ] Microbiology Information
- [ ] New Item
- [ ] Packaging Information
- [ ] Stability Information
- [ ] REMS Final
- [ ] REMS Assessment
- [ ] REMS Assessment Methodology
- [ ] REMS Revision
- [ ] REMS Modification-Due to Safety Labeling Changes
- [ ] REMS Modification-Major
- [ ] REMS Modification-Minor
- [ ] REMS Proposal-Standard
- [ ] REMS Correspondence
- [ ] Agent Appointment
- [ ] Other *(Specify)*:

DMF Information
Fields 8 (Scenario 2)

7. Submission Type *(May select more than one)*

- ☐ Original (New)
- ☒ Administrative Amendment
- ☐ Annual Report
- ☐ Letter of Authorization
- ☐ Withdrawal of Letter of Authorization
- ☐ Meeting
- ☐ Quality Amendment
- ☐ Response to Administrative Filing Issue
- ☐ Response to Deficiency, Complete Response, Information Request or Additional Comments Letter
- ☐ REMS - Risk Evaluation and Mitigation Strategy
- ☐ Other *(Specify)*:

8. Amendment Type, if applicable *(May select more than one)*

- ☐ Change of agent/address/contact person
- ☒ Change of holder/address/contact person
- ☐ Change of DMF Subject (title)
- ☐ Change of DMF Type
- ☐ Meeting Package
- ☐ Meeting Request
- ☐ Controls Information
- ☐ Facility Information
- ☐ Formulation Information
- ☐ Manufacture Information
- ☐ Microbiology Information
- ☐ New Item
- ☐ Packaging Information
- ☐ Stability Information
- ☐ REMS Final
- ☐ REMS Assessment
- ☐ REMS Assessment Methodology
- ☐ REMS Revision
- ☐ REMS Modification-Due to Safety Labeling Changes
- ☐ REMS Modification-Major
- ☐ REMS Modification-Minor
- ☐ REMS Proposal-Standard
- ☐ REMS Correspondence
- ☒ Agent Appointment
- ☐ Other *(Specify)*:

DMF Information
Fields 8 (Scenario 3)

7. Submission Type *(May select more than one)*

- ☐ Original (New)
- ☐ Administrative Amendment
- ☐ Annual Report
- ☐ Letter of Authorization
- ☐ Withdrawal of Letter of Authorization
- ☐ Meeting
- ☒ Quality Amendment
- ☐ Response to Administrative Filing Issue
- ☐ Response to Deficiency, Complete Response, Information Request or Additional Comments Letter
- ☐ REMS - Risk Evaluation and Mitigation Strategy
- ☐ Other *(Specify)*:

8. Amendment Type, if applicable *(May select more than one)*

- ☐ Change of agent/address/contact person
- ☐ Change of holder/address/contact person
- ☐ Change of DMF Subject (title)
- ☐ Change of DMF Type
- ☐ Meeting Package
- ☐ Meeting Request
- ☒ Controls Information
- ☐ Facility Information
- ☐ Formulation Information
- ☐ Manufacture Information
- ☐ Microbiology Information
- ☐ New Item
- ☐ Packaging Information
- ☒ Stability Information
- ☐ REMS Final
- ☐ REMS Assessment
- ☐ REMS Assessment Methodology
- ☐ REMS Revision
- ☐ REMS Modification-Due to Safety Labeling Changes
- ☐ REMS Modification-Major
- ☐ REMS Modification-Minor
- ☐ REMS Proposal-Standard
- ☐ REMS Correspondence
- ☐ Agent Appointment
- ☐ Other *(Specify)*:

DMF Information
Fields 8 (Scenario 4)

7. Submission Type *(May select more than one)*

- ☐ Original (New)
- ☒ Administrative Amendment
- ☐ Annual Report
- ☐ Letter of Authorization
- ☐ Withdrawal of Letter of Authorization
- ☐ Meeting
- ☒ Quality Amendment
- ☐ Response to Deficiency, Complete Response, Information Request or Additional Comments Letter
- ☐ REMS - Risk Evaluation and Mitigation Strategy
- ☐ Response to Administrative Filing Issue
- ☐ Other *(Specify)*:

8. Amendment Type, if applicable *(May select more than one)*

- ☐ Change of agent/address/contact person
- ☐ Change of holder/address/contact person
- ☒ Change of DMF Subject (title)
- ☐ Change of DMF Type
- ☐ Meeting Package
- ☐ Meeting Request
- ☐ Controls Information
- ☐ Facility Information
- ☐ Formulation Information
- ☐ Manufacture Information
- ☐ Microbiology Information
- ☐ New Item
- ☒ Packaging Information
- ☐ Stability Information
- ☐ REMS Final
- ☐ REMS Assessment
- ☐ REMS Assessment Methodology
- ☐ REMS Revision
- ☐ REMS Modification-Due to Safety Labeling Changes
- ☐ REMS Modification-Major
- ☐ REMS Modification-Minor
- ☐ REMS Proposal-Standard
- ☐ REMS Correspondence
- ☒ Agent Appointment
- ☐ Other *(Specify)*:

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.)*

City	State/Province/Region
Buckystown	California

Country	ZIP or Postal Code
USA	20814

Establishment DUNS Number	Registration (FEI) Number
123456789	9876543210

Is the establishment new to the DMF?
☐ Yes ☒ No

Establishment Role *(e.g. manufacturing step, type of testing)*
Manufacturing

Is the establishment ready for inspection? *(See instructions)*
☐ Yes ☒ No If not, when will site be ready? *(See instructions)* 10/25/2021

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**

Click this button to delete page. May be repeated as needed. **Delete Page**

DMF Information
Field 10

10. Cross-Referenced DMF(s)

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

DMF Information
Certification & Fields 11 to 15

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 Regulatory Affaris	12/20/2020

13. Telephone Number *(Include country code, if applicable, and area code)*	14. FAX Number *(Include country code, if applicable, and area code)*
(222) 123-4567	not available

15. Email Address
JSmith@abccompany.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

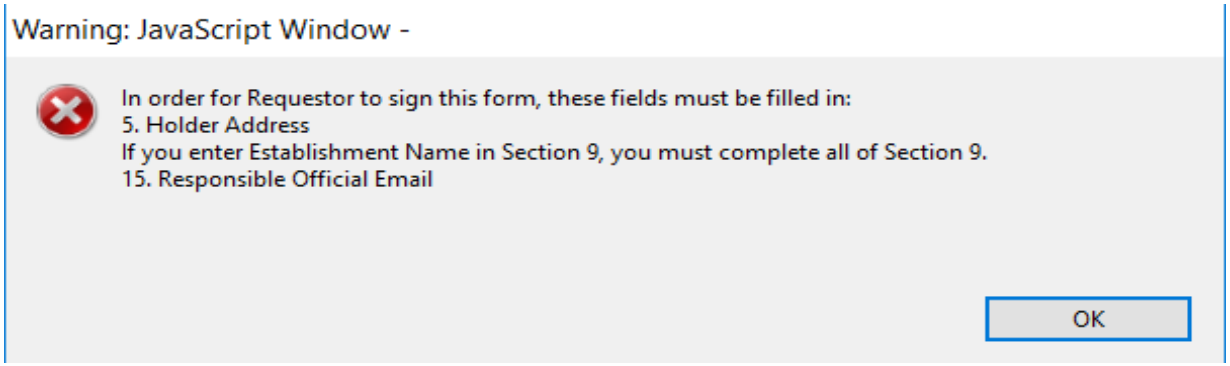
City	State/Province/Region	ZIP or Postal Code
Laurel	Virginia	22046

Country
USA

17. Signature of Person Named in Item 11

Sign

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."

FAQs – Form 3938

Question Can a contracted company sign DMF Form 3938?

Answer **No**. A third party (contracted company) cannot sign DMF Form 3938.

FAQs – Form 3938

Question Can a DMF Agent sign DMF Form 3938?

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

FAQs – 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?

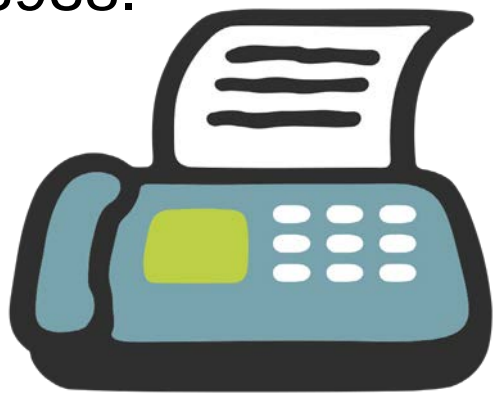
Answer It is acceptable for another employee to sign on behalf a company's Responsible Official as long as the signed form reflects the Responsible Official's name in Field 11.

FAQs – Form 3938

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.



FAQs – Form 3938

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-regulatory-submission-and-review/requesting-pre-assigned-application-number

FAQs – Form 3938

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.

FAQs – Form 3938

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

FAQs – Form 3938

Question 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

FAQs – Form 3938

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

Answer **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)

FAQs – Form 3938

Question Can a DMF be held by multiple entities?

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

FAQs – Form 3938

Question How does the Agency define the DMF Holder?

Answer 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.

FAQs – Form 3938

Question Is a DMF Holder required to appoint a U.S. Agent?

Answer 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.

FAQs – Form 3938

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

Answer 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.

FAQs – Form 3938

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

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

FAQs – Form 3938

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

Answer The form does require an entry in these fields to avoid an error. If an FEI/DUNS is not available just enter “9999999999” (10 digits) in an FEI field or “999999999” (9 digits) in a DUNS field. This will allow the form to be finalized.

FAQs – Form 3938

Question Should I still provide a cover letter with my submissions?

Answer 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.

FAQs – Form 3938

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

Answer 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

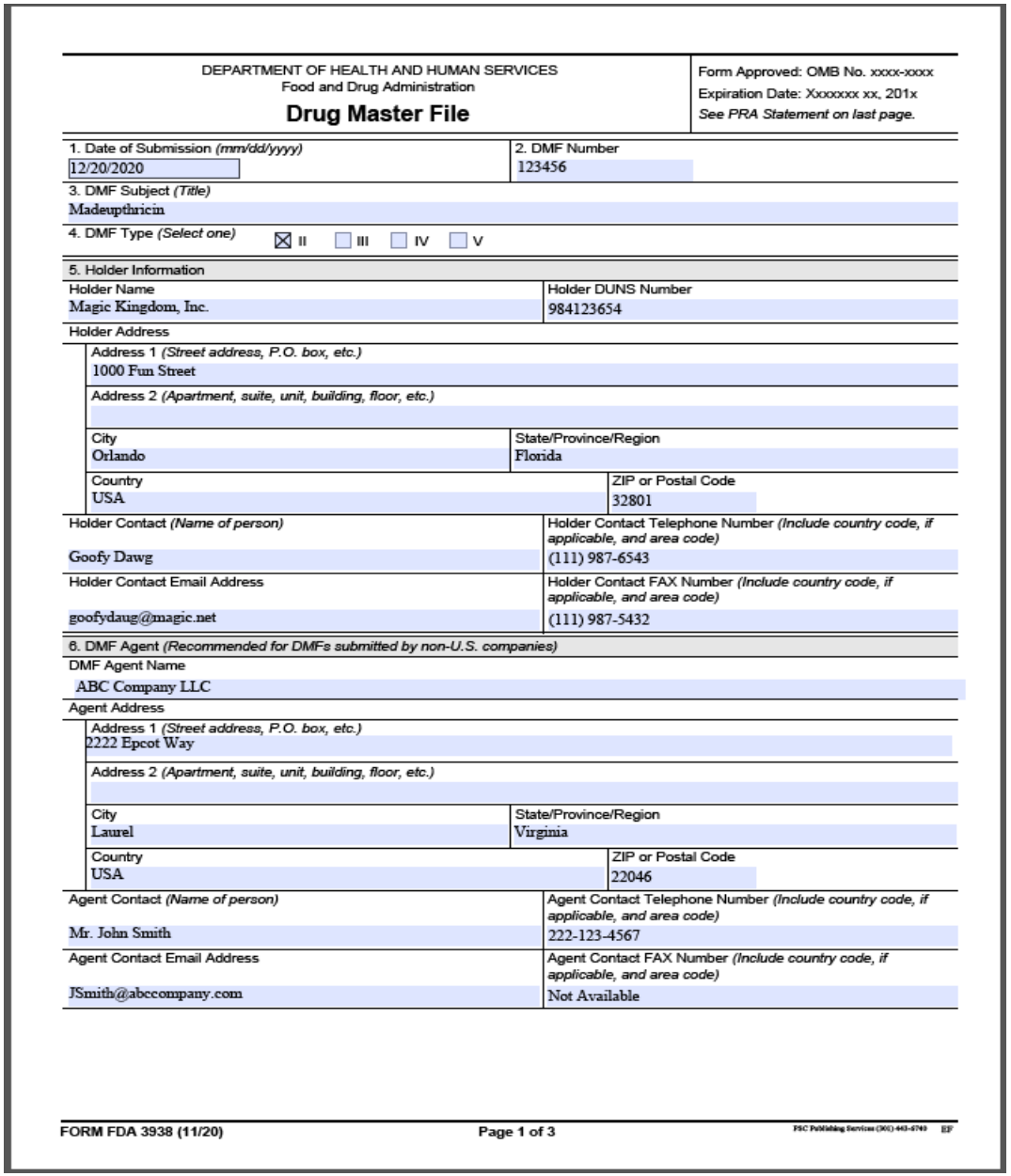
eCTD Website:

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

DMF Questions:

dmfquestion@fda.hhs.gov

Completed Form (Page 1)



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Master File

Form Approved: OMB No. xxxx-xxxx
Expiration Date: Xxxxxxx xx, 201x
See PRA Statement on last page.

1. Date of Submission *(mm/dd/yyyy)*: 12/20/2020

2. DMF Number: 123456

3. DMF Subject *(Title)*: Madeupthricin

4. DMF Type *(Select one)*: ☒ II ☐ III ☐ IV ☐ V

5. Holder Information

Holder Name: Magic Kingdom, Inc.

Holder DUNS Number: 984123654

Holder Address

Address 1 *(Street address, P.O. box, etc.)*: 1000 Fun Street

Address 2 *(Apartment, suite, unit, building, floor, etc.)*:

City: Orlando

State/Province/Region: Florida

Country: USA

ZIP or Postal Code: 32801

Holder Contact *(Name of person)*: Goofy Dawg

Holder Contact Telephone Number *(Include country code, if applicable, and area code)*: (111) 987-6543

Holder Contact Email Address: goofydaug@magic.net

Holder Contact FAX Number *(Include country code, if applicable, and area code)*: (111) 987-5432

6. 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: Laurel

State/Province/Region: Virginia

Country: USA

ZIP or Postal Code: 22046

Agent Contact *(Name of person)*: Mr. John Smith

Agent Contact Telephone Number *(Include country code, if applicable, and area code)*: 222-123-4567

Agent Contact Email Address: JSmith@abccompany.com

Agent Contact FAX Number *(Include country code, if applicable, and area code)*: Not Available

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Completed Form (Page 2)

7. Submission Type *(May select more than one)*

- ☐ Original (New)
- ☒ Administrative Amendment
- ☐ Annual Report
- ☐ Letter of Authorization
- ☐ Withdrawal of Letter of Authorization
- ☐ Meeting
- ☒ Quality Amendment
- ☐ Response to Administrative Filing Issue
- ☐ Response to Deficiency, Complete Response, Information Request or Additional Comments Letter
- ☐ REMS - Risk Evaluation and Mitigation Strategy
- ☐ Other *(Specify)*:

8. Amendment Type, if applicable *(May select more than one)*

- ☐ Change of agent/address/contact person
- ☐ Change of holder/address/contact person
- ☒ Change of DMF Subject (title)
- ☐ Change of DMF Type
- ☐ Meeting Package
- ☐ Meeting Request
- ☐ Controls Information
- ☐ Facility Information
- ☐ Formulation Information
- ☐ Manufacture Information
- ☐ Microbiology Information
- ☐ New Item
- ☒ Packaging Information
- ☐ Stability Information
- ☐ REMS Final
- ☐ REMS Assessment
- ☐ REMS Assessment Methodology
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- ☐ REMS Modification-Due to Safety Labeling Changes
- ☐ REMS Modification-Major
- ☐ REMS Modification-Minor
- ☐ REMS Proposal-Standard
- ☐ REMS Correspondence
- ☐ Agent Appointment
- ☐ Other *(Specify)*:

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.)*:	
City: Buckystown	State/Province/Region: California
Country: USA	ZIP or Postal Code: 20814
Establishment DUNS Number: 123456789	Registration (FEI) Number: 9876543210

Is the establishment new to the DMF?

☐ Yes ☒ No

Establishment Role *(e.g. manufacturing step, type of testing)*: Manufacturing

Is the establishment ready for inspection? *(See instructions)*

☐ Yes ☒ No If not, when will site be ready? *(See instructions)* 10/25/2021

Establishment Contact *(Name of person)*: Ms. Jane Doe	Establishment Contact Telephone Number *(Include country code, if applicable, and area code)*: 301-234-8758
Establishment Contact Email Address: JaneDoe@healthpath.com	Establishment Contact FAX Number *(Include country code, if applicable, and area code)*: 301-234-8700

Click this button to add entries for an additional establishment. May be repeated as needed. **Add Establishment**

Click this button to delete page. May be repeated as needed. **Delete Page**

FORM FDA 3938 (11/20) Page 2 of 3

Completed Form (Page 3)

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 Regulatory Affairs	12/20/2020

13. Telephone Number *(Include country code, if applicable, and area code)*	14. FAX Number *(Include country code, if applicable, and area code)*
(222) 123-4567	not available

15. Email Address

JSmith@abccompany.com

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/Region	ZIP or Postal Code
Laurel	Virginia	22046

Country: USA

17. Signature of Person Named in Item 11 — Sign

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."