

Drug Master File

1. Date of Submission (mm/dd/yyyy)		2. DMF Number	
3. DMF Subject (Title)			
4. DMF Type (Select one) ☐ II ☐ III ☐ IV ☐ V			
5. Holder Information			
Holder Name		Holder DUNS Number	
Holder Address			
Address 1 (Street address, P.O. box, etc.)			
Address 2 (Apartment, suite, unit, building, floor, etc.)			
City		State/Province/Region	
Country		ZIP or Postal Code	
Holder Contact (Name of person)		Holder Contact Telephone Number (Include country code, if applicable, and area code)	
Holder Contact Email Address		Holder Contact FAX Number (Include country code, if applicable, and area code)	
6. DMF Agent (Recommended for DMFs submitted by non-U.S. companies) or Holder Representative at Alternate Address			
DMF Agent Name			
Agent Address			
Address 1 (Street address, P.O. box, etc.)			
Address 2 (Apartment, suite, unit, building, floor, etc.)			
City		State/Province/Region	
Country		ZIP or Postal Code	
Agent Contact (Name of person)		Agent Contact Telephone Number (Include country code, if applicable, and area code)	
Agent Contact Email Address		Agent Contact FAX Number (Include country code, if applicable, and area code)	

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 <i>(Specify)</i> : _____ |

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

- | | | |
|---|-----------------------------|--|
| Change of agent/address/contact person | Manufacture Information | REMS Modification-Due to Safety Labeling Changes |
| Change of holder/address/contact person | Microbiology Information | |
| 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 |
| Controls Information | REMS Assessment | Agent Appointment |
| Facility Information | REMS Assessment Methodology | Other <i>(Specify)</i> : _____ |
| Formulation Information | REMS Revision | |

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

Establishment Address

Address 1 *(Street address)*Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City

State/Province/Region

Country

ZIP or Postal Code

Establishment DUNS Number

Registration (FEI) Number

Is the establishment new to the DMF?

☐ Yes☐ NoEstablishment Role *(e.g. manufacturing step, type of testing)*Is the establishment ready for inspection? *(See instructions)*☐ Yes☐ NoIf not, when will site be ready? *(See instructions)* _____Establishment Contact *(Name of person)*Establishment Contact Telephone Number *(Include country code, if applicable, and area code)*

Establishment Contact Email Address

Establishment Contact FAX Number *(Include country code, if applicable, and area code)**Click this button to add entries for an additional establishment. May be repeated as needed.**Click this button to delete page. May be repeated as needed.*

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)	
13. Telephone Number (Include country code, if applicable, and area code)		14. FAX Number (Include country code, if applicable, and area code)	
15. Email Address			
16. Address of Person Named in Item 11			
Address 1 (Street address or P.O. box, company name)			
Address 2 (Apartment, suite, unit, building, floor, etc.)			
City		State/Province/Region	
Country		ZIP or Postal Code	
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."