

TRANSMITTAL (COVER) LETTER FOR LETTERS OF AUTHORIZATION,
AMENDMENTS AND ANNUAL REPORTS

Notes are in **bold font**. Information to be filled in is in *italics*

Date: *Enter the date of this Submission*

DMF#: *Enter the DMF number*

Holder: *Enter the Name of Holder*

Subject (Title): *Enter the Subject (Title) of the DMF as it appears on the DMF Web site.*
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm>

Submission Information: *Enter the Type of Submission, Categories and Sub categories that apply*

Dear DMF Staff

Include a summary of the changes covered by the submission.

Sincerely,

Signature of Responsible Official

Enter

Name of Responsible Official

Responsible Official's Title

Responsible Official's Company i.e. Holder or Agent

Responsible Official's Telephone number

Responsible Official's Fax number

Responsible Official's e-mail address

Submission Types, Categories and Subcategories

Submission Type	Category	Subcategory
Letter of Authorization	Letter of Authorization	Letter of Authorization
		Withdrawal of Letter of Authorization
Annual Report	Annual Report	New
		Amendment
General information	Closure	Not applicable
	Reactivation	Not applicable
	Administrative	Change in the agent name or address
		Change in the contact person at the holder or agent
		Change in the subject of the DMF
		Change in the type of DMF
		Transfer of DMF to New Holder
		Change in Holder Name
		New Holder Acceptance
Agent Appointment		
Original	Quality	New item
		Controls Information (specifications)
		Dissolution Data
		Facility Information (changes in manufacturing and or testing sites)
		Formulation Information
		Lot Release (batch analysis)
		Manufacture Information
		Microbiology Information
		New Strength
		Quality (Not covered by other subcategories)
		Packaging Information
		Stability Information
		Response to Information Request
		Response to Deficiency Letter
Response to Complete Response Letter		

Multiple Submissions/categories/subcategories (including Annual Reports) may be submitted at the same time. These should be listed in the Submission Type field of the heading of the Cover Letter.