

How to submit a LOA to the agency

Preamble:

LOAs created and processed in our front- / backend web-application and copies thereof stored at present in our LN-database "Letter of Authorization PP". After submitting the original signed LOA to the agency a .pdf-copy of the LOA will be send to the customer.










Note to DMF Types:

Canada: Type II

USA: Type III

CANADA

Letter of Access (LOA) to Health Canada (HC) in non-eCTD electronic format

Step	Action	Info
1	<p>Create folder structure on CD or USB stick with your DMF Number</p> <p>Label main folder related to your DMF number, example: </p> <p>a. "HC6-024-f" is given from HC and never to be changed</p> <p>b. add your "DMF Number" e.g. 2011-059 without "-"</p> <p>c. ends up as folder name: HC6-024-f2011059</p>	<ul style="list-style-type: none"> [-]  HC6-024-fDMFNumber <ul style="list-style-type: none"> [-]  m1 <ul style="list-style-type: none"> [-]  1.0.1 Correspondence <ul style="list-style-type: none">  1.0.1 Cover Letter [-]  1.2 Administrative Information <ul style="list-style-type: none">  1.2.1 Application Forms  1.2.2 Fee Forms  1.2.6 Authorization for Sharing Information
2	<p>Store files as .pdf into folders</p>	<p>1.2.1 : Application Form, <u>duly filled</u></p> <p>1.2.2 : Fee Form, current version, blanc</p> <p>1.2.6 : LOA, signed</p>
Note	<p>Application Form: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/forms.html</p> <p>Please choose: "Drug Master File (DMF) Application Form"</p>	
Note	<p>Fee Form: (amount of payment will increase every year, so please use current form) https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/forms.html</p> <p>Please choose: "Master File (MF) Application Fee Form for Human Drugs"</p>	
Note	<p>If you issue multiple LOAs referencing to the <u>same</u> DMF-No., then the LOAs can be stored on the same CD/USB. Otherwise, a separate data storage- device must be used for each DMF.</p>	
3	<p>Arrange final package to ship: Three hardcopy's + CD or USB</p>	<p>CD or USB + hardcopy of: - LOA (serves as cover letter)</p>

		- Fee Form, <u>duly filled</u> - Payment receipt if paid by wire
4 Note	Ship all to:	Master File Administration Unit Therapeutic Products Directorate Health Products and Food Branch Finance Building, 2nd Floor Address Locator: 0201A 101 promenade Tunney's Pasture Driveway Ottawa, Ontario K1A 0K9 You will get a LOA-acknowledgement (e-mail)

USA

Letter of Authorisation (LOA) to the Food and Drug Administration (FDA) as paper format

Step	Action	Info
1	Two hardcopy's needed:	- LOA, original signed - One copy of original LOA
2 Note	Ship all to:	Food and Drug Administration Center for Drug Evaluation and Research Central Document Room 5901-B Ammendale Road Drug Master File Staff Beltsville MD 20705-1266 No feedback/ acknowledgement here from the FDA.