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New Master File Application Form: Notice

May 1, 2023

Our file number: 23-102532-292

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Background

Health Canada is revising the Master File Application Form and merging it with the Master File Application Fee Form. This will streamline the application process and reduce the administrative burden on master file holders.

This new, single, web-based Master File Application form will generate an XML file. This format makes it easier to upload data into internal Health Canada systems, enhancing accuracy, consistency and reliability of the information captured. It uses drop-down lists, predictive text and help text to support easier and faster data entry.

This new web-based XML Master File Application Form will be required to file master file transactions for human use **effective June 26, 2023** (excluding veterinary master file transactions).

Important information

The new Master File Application Form will be effective as of June 26, 2023. We will reject transactions received on or after June 26 if you do not file them using the new application form.

The new web-based form will replace the existing PDF versions of the Master Application Form and the Master File Application Fee Form.

The XML form will be posted to:

- [Forms: Applications and submissions for drug products](#)
- [Master Files \(MFs\) – Procedures and Administrative Requirements](#)

The form will have detailed instructions on how to complete and generate the MF XML file.

You will have to provide the form with every eCTD and non-eCTD transaction that you send through the Common Electronic Submissions Gateway.

The placement of the form is in section 1.2.1 Application Forms. Do **not** include a separate fee form under section 1.2.2 Fee Forms.

The fields on the Master File Application Form will be built interdependently, meaning there will be picklists tailored to the selections you make in previous fields. Make sure you select the correct items from the picklists.

Do **not** send fee payment with your master file transaction. Health Canada will:

1. verify the transaction type

2. assign the appropriate fee
3. issue an invoice once the transaction is deemed administratively complete

Funding and Fees

Before you complete the new form

1. Decide if you're sending the Master File.xml file in Electronic Common Technical Document (eCTD) format or non-eCTD format:
 - You must file all new master files in the eCTD format.
 - If a master file is currently in non-eCTD format, we will still accept transactions such as updates or letters of access in non-eCTD format.
2. Read the relevant guidance documents and supporting documents:
 - Guidance Document: Master Files (MFs) - Procedures and Administrative Requirements
 - Guidance Document: Preparation of Regulatory Activities in non-eCTD format
 - Guidance Document: Preparation of Regulatory Activities in eCTD Format and Health Canada Reference Guide
 - Available on request.
 - Organisation and Document Placement for Canadian Module 1
 - Available on request
3. Obtain Common Electronic Submissions Gateway accounts:
 - If you don't have an account, refer to:
 - Guidance Document: Preparation of Regulatory Activities in non-eCTD format
 - or**
 - Guidance Document: Preparation of Regulatory Activities in eCTD Format and Health Canada Reference Guide
4. Obtain a dossier ID (if needed):

- Dossier Identifier for Master Files filed in eCTD is a lower case 'e' followed by 6 digits.
 - Fill out the [Dossier ID Request Form for Master File Dossiers](#).
- Dossier Identifier for Master Files filed in non-eCTD is a lower case 'f' followed by 7 digits.
 - If you do not know your master file number, please contact the Master File Administration Unit.

Contact us

Contact the Master File Administration Unit with questions about the master file registration process.

Email : dmf.enquiries-fmm@hc-sc.gc.ca

Contact Cost Recovery with questions about fees or invoices.

Email : cost.recovery@hc-sc.gc.ca

Contact eReview with general questions about the new form and filing through the electronic gateway.

Email : ereview@hc-sc.gc.ca

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