Health Canada Santé Canada

Protected B when completed

Authorization for a third party to file a regulatory activity on behalf of the manufacturer/sponsor

All fields in this document are required*.

Section A: Authorization

Manufacturer/Sponsor first and last name:
Third party individual:
Third party company name:
Name of product:
Drug manufacturer/sponsor name:
☐ By checking this box, I authorize the third party individual to file a regulatory activity for this product on behalf of the drug manufacturer or sponsor.

Section B: Signature

First and last name:	
Title:	
Manufacturer / Sponsor name:	
Signature:	Date (yyyy-mm-dd):

Section C: Notes/Requirements

1. A Third Party Authorization letter is required within the initial transaction of a regulatory activity when the:
   - Regulatory contact for this regulatory activity, indicated on the RT file, is a third party acting on behalf of the manufacturer/sponsor; and
   - Regulatory activity type is one of the following (including administrative submissions): NDS (New Drug Submission), NDS CV (New Drug Submission with flexibilities for Designated COVID-19 Drug), NDS-D (New Drug Submission - Disinfectant), SNDS (Supplement to a New Drug Submission), SNDS-C (Supplement to a New Drug Submission-Confirmatory), SNDS-D (Supplement to a New Drug Submission - Disinfectant), ANDS (Abbreviated New Drug Submission), SANDS (Supplement to an Abbreviated New Drug Submission), SANDS-C (Supplement to an Abbreviated New Drug Submission-Confirmatory), NC (Notifiable Change), EUNDS (Extraordinary Use New Drug Submission), EUSNDS (Supplement to an Extraordinary Use New Drug Submission), EUANDS (Abbreviated Extraordinary Use New Drug Submission), EUSANDS (Supplement to an Abbreviated Extraordinary Use New Drug Submission), DINA (Application for Drug Identification Number), DINB (Application for Drug Identification Number - Biologic), DIND (Application for Drug Identification Number - Disinfectant), DINF (Application for Drug Identification Number - Category IV Monograph Product), DINV (Application for Drug Identification Number – Veterinary), PDC (Post-Authorization Division 1 Change), PDC-B (Post-Authorization Division 1 Change – Biologic), PRORE (Protocol Review), YBPR (Yearly Biologic Product Report).

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2. The authorization letter is only required once per regulatory activity unless the third party has changed, in which case a new authorization letter will be required. The authorization letter should be provided as a separate PDF document.
3. Even if the Third Party Authorization letter from a previous regulatory activity is still valid (same contact), it needs to be provided again within the initial transaction of the new regulatory activity.