Health Canada — Santé Canada

Pre-submission meeting request

Veterinary Drugs Directorate - Health Products and Food Branch (HPFB)

As part of Health Canada's efforts to move towards a common submission intake across product lines, the Veterinary Drugs Directorate (VDD) has transitioned to a fully electronic submission environment with the Regulatory Enrolment Process (REP). Use of the REP became mandatory as of October 1, 2022 for veterinary drug submissions that are within scope (including pre-submission meeting requests). Detailed information regarding the REP is available on the REP information page.

If this is your first time filing through REP, please contact VDD at vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca for more information, guidance, and support.

For meetings that do not relate to a specific drug product (e.g., pipeline meetings), sections 3 and 6 may not be applicable.

All fields indicated by an asterisk (*) are mandatory.

1. Sponsor contact information	
Name (with Salutation - Mr., Mrs., Ms., Dr.)*:	
Title*:	
Company*:	
Address*:	
Telephone number*:	
Email*:	

2. DIN owner name and address (if different from above) of the drug product for which the submission is to be filed	
DIN owner name:	
Address:	

Canada

3. Product information (note: If more than one product, copy item 3's table)

Product Name:	
Proper/common/chemical name:	
Proposed active ingredient(s) and strength(s):	
Proposed dosage form(s) of the drug:	
Proposed therapeutic classification:	
Proposed indication(s):	
Proposed species:	

4. Purpose of the meeting

Check an applicable box*:

Pre-New Drug Submission (NDS)

Pre-Supplemental NDS

Pre-Abbreviated NDS(ANDS)

Pre-Supplemental ANDS

Pipeline

Other (please specify):

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5. Listing of 3-4 proposed dates (approximately 2 months following the request date) and the time of the day for each of the proposed meeting dates. Please also specify whether a teleconference, Web Ex, or Microsoft Teams meeting is being requested. If selecting Web Ex or Microsoft Teams, a teleconference number will be needed as a backup plan.

Note: Separate sheet attached if necessary

Date*	Time*	A.M. or P.M.*	Teleconference, Web Ex, or Microsoft Teams*
		A.M. P.M.	Teleconference Web Ex Microsoft Teams
		A.M. P.M.	Teleconference Web Ex Microsoft Teams
		A.M. P.M.	Teleconference Web Ex Microsoft Teams
		A.M. P.M.	Teleconference Web Ex Microsoft Teams

6. A brief description of the drug product and corresponding submission plan:

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7. A copy of the proposed meeting agenda (note: the final agenda should be very similar to the proposed version)*:

8. A list of specific items or questions that require guidance from VDD (grouped by scientific disciplines)*:

9. Request to have the meeting with the following divisions from VDD*:

Clinical Evaluation Division (animal safety and efficacy)

Human Safety Division

Quality Evaluation Division

Regulatory Operations and Policy Division (general submission information, procedure, and process)

Request date*:	
Requested by*:	

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