Health Canada Santé Canada

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Veterinary Drugs Directorate
Health Products and Food Branch (HPFB)

Pre-Submission Meeting Request

If the total attachments are less than 20 megabytes, you may send the request form by email to vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca.

For meetings that do not relate to a specific drug product, or is to discuss upcoming submissions, (pipeline meeting) then sections 2, 3 and 6 may be not be applicable.

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	

3. Product Information:

a) Product Name	
b) Proper/common/chemical name	

Canada

c) Proposed active ingredient(s) and strength(s)	
d) Proposed dosage form(s) of the drug	
e) Proposed therapeutic classification	
f) Proposed indication(s)	
g) Proposed species	

If more than one product, copy item 3's table.

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):

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 face-to-face meeting, teleconference, or Web Ex is being requested. If selecting Web Ex, a teleconference number will be needed as a backup plan.

Date	Time	a.m. or p.m	Face-to-face or Teleconference or Web Ex

Note: Separate sheet attached if necessary

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

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
- ☐ Manufacturing and Chemical Evaluation Division
- ☐ Submission and Knowledge Management Division (general submission information, procedure and process)

Request date: Requested by: