Health Canada Santé Canada

Veterinary drugs- Management of regulatory submissions guidance

November 2021

Canada

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To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: publications@hc-sc.gc.ca

Publication date: November 2021

Cat.: H164-324/2021E-PDF
ISBN: 978-0-660-40655-8
Pub.: 210394

Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

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1. Introduction

This guidance will inform sponsors about the process the Veterinary Drugs Directorate (VDD) of Health Canada follows for managing regulatory submissions and related information filed by submission applicants (referred to as sponsors hereafter). This process aligns with the *Food and Drugs Act* and the *Food and Drug Regulations* where all drugs, unless specifically exempted, must be authorized before being sold or imported for sale in Canada. The VDD is the regulatory authority for the administration of the *Food and Drugs Act* and regulations for the sale of drugs intended for use in animals.

This document also provides guidance to sponsors on how to comply with the *Food and Drugs Act* and regulations and VDD's policies.

1.1 Scope and application

This guidance applies to veterinary submission types including:

- new drug submission (NDS)
- supplemental new drug submission (SNDS)
- abbreviated new drug submission (ANDS)
- supplemental abbreviated new drug submission (SANDS)
- notifiable change (NC)
- drug identification number (DIN) application and change to DIN
- administrative NDS/ANDS or DIN submission filed in support of manufacturer name change, change in product ownership, merger/buyout, additional product name and licensing agreements
- administrative SNDS/SANDS or DIN submission filed in support of a product name change
- experimental studies certificate (ESC) application and ESC amendments
- protocol reviews
- investigational new drug submissions (INDs) and IND amendments

Please contact the Submission and Knowledge Management Division (SKMD) at vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca for further guidance on protocol reviews.

Processes to notify a veterinary health product (VHP) or to seek access to a veterinary drug through the Emergency Drug Release (EDR) program are not within the scope of this document. For information about our VHP Notification program, please contact vhp-psa@hc-sc.gc.ca. For information about the EDR program, please contact edr-dmu@hc-sc.gc.ca.

Submissions filed under joint review or simultaneous review initiatives with other regulatory jurisdictions (for example, Regulatory Cooperation Council [RCC] initiative with the U.S. Food and Drug Administration's Center for Veterinary Medicine) may be subject to provisions outside of this guidance document. Contact the VDD for submissions filed under joint or simultaneous reviews at vdd.vetdrugs-medsvet.dmv@hc-sc.gc.ca.

For each of the applicable submission types, this guidance outlines the process for each stage of the submission review and approval process, including the:

- pre-submission phase
- initial processing of submission
- screening of submission
- review of submission
- final review decision

The VDD will apply the same submission management principles during each stage of the submission review and approval process. The VDD will make related decisions within its performance targets (see Appendix A).

Information regarding the following regulatory activities is included:

- administrative amendments to submissions under review
- unsolicited amendments to submissions under review
- withdrawal of submissions under review
- refiled submissions
- post-approval obligations
- access to submission-related information

In summary, this is an administrative procedural document. Sponsors should consult the *Food and Drugs Act* and regulations as well as applicable Health Canada policies and scientific guidance documents to ensure that all required data components are included at the time of filing.

2. An overview of regulatory submission types for veterinary drugs

2.1 Request for authorization to sell a drug that does not have a DIN

A researcher may seek authorization to permit the sale of a drug without a DIN:

- as part of a veterinary drug study, such as preliminary research
- to generate data to support a veterinary drug regulatory submission in Canada

A drug without a DIN may be sold when 1 of the following submissions are filed and a written authorization is obtained from the VDD:

- an experimental studies certificate (ESC)
- a pre-clinical submission (referred to as an investigational new drug (IND) submission)

2.2 Request for marketing authorization

A drug must have a valid DIN to be sold or imported for sale (referred to as sold hereafter) in Canada. The sponsor can, depending on the drug in question, submit 1 of the listed regulatory submissions to the VDD for their request to obtain a DIN for selling a veterinary drug in Canada:

- a drug identification number (DIN) submission
- a new drug submission (NDS)
- an abbreviated NDS (ANDS)

2.3 Post-approval authorizations: Scientific amendments to initial marketing authorization

2.3.1 Filing updated information

After a sponsor has received a marketing authorization for a new drug, the sponsor needs to file certain updated information or changes to the new drug prior to implementation. Depending on the nature of the changes made, the sponsor needs to file 1 of the submission types:

- supplement to a new drug submission (SNDS) or supplement to an abbreviated new drug submission (SANDS)
- notifiable change (NC) submission
- level III notification (not subject to review and approval)

If a sponsor is seeking to make a change to the marketing authorization for a drug that is not a "new drug," the sponsor needs to file a:

- change to DIN application

2.3.2 Reactivation of a cancelled DIN by Health Canada

Either Health Canada or the DIN holder can cancel the DIN for a drug in accordance with Section C.01.014.6 of the *Food and Drug Regulations*.

Once a DIN has been cancelled, the sponsor needs to submit a new submission to re-gain marketing approval for a product. The VDD may permit cross references to previously filed information. However, the VDD may also require additional information to ensure that the submission complies with the current regulations and guidelines.

3. Procedure for sending regulatory submissions and related information

Sponsors should send all submissions to the VDD in electronic-only format as per *Guidance Document: Preparation of Drug Regulatory Activities in the Non-eCTD Electronic-Only Format*. Sponsors may use e-mail if the file size is less than 20 MB.

The VDD strongly encourages the use of the regulatory enrolment process (REP), which allows the filing of submissions via the common electronic submission gateway (CESG), for submissions that are within scope of REP.

Sponsors wishing to file via REP can consult the REP guidance documents or e-mail eReview@hc-sc.gc.ca for information on procedures and guidances in effect at the time of filing.

To discuss alternate methods of submission filing, please contact the Submission and Knowledge Management Division (SKMD) at vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca.

4. Submission holds

The VDD may place a submission on hold at various stages of the submission process. In the case of a submission hold, the VDD will inform the sponsor of the reason and the possible solutions (if available).

4.1 During initial processing

The VDD will place the submission on hold if the information received in a submission does not meet all applicable administrative requirements, for example:

- the file path name is too long
- forms are missing or not signed
- the submission did not follow non-eCTD electronic only format

The VDD will send an e-mail to the sponsor to:

- explain the reason(s) for the process hold
- request that the sponsor provide a response within a specified number of days

The VDD may reject the submission if the sponsor does not provide a response to the VDD within the time specified. The official date of receipt will be when the submission is administratively complete. This will be considered the filing date.

4.2 During screening, review and the notice of compliance (NOC) and/or DIN issuance stage

The VDD may place a submission on hold in certain situations that prevent further review or issuance of a decision. These situations may include:

- administrative issues
- outstanding regulatory issues with the product for which the submission was filed
- patent concerns, or the sponsor of the submission did not provide the required patent-related information and the submission is placed on a patent hold by Office of Patented Medicines and Liaison

5. Pre-submission phase

5.1 Consultation: pre-submission

Before filing a submission, the sponsor should consult the applicable guidance documents. For a product that is already approved, the sponsor should refer to the applicable post-NOC guidance documents to ensure that the proposed change qualifies for the submission type under which the sponsor plans to file. In cases where available VDD guidance does not cover all aspects of an intended submission, a pre-submission meeting may be useful to the sponsor.

5.2 Classification

The sponsor may need guidance on the classification of their product, for example, whether it would be regulated as a new drug, not new drug, VHP, feed, pesticide, etc. In this case, the sponsor should send a request for product classification to the VDD at classification-vet@hc-sc.gc.ca.

For inquiries related to submission classification (for example, SNDS versus NC), the sponsor may send a request for regulatory guidance to the VDD via e-mail. Sponsors should provide adequate information to enable the VDD to assess the significance of the changes proposed without the need for further clarification from the sponsor.

It is the sponsor's responsibility to provide adequate supporting data for the proposed change in order to demonstrate that the changes do not pose any adverse impact on:

- the chemistry and manufacturing
- target animal safety and efficacy
- human safety aspects of the drug product

The VDD will:

- provide guidance based on the information provided by the sponsor
- verify the submission classification based on the information provided at the time of the submission filing
- re-classify the submission if it contains additional changes or if the overall changes are considered beyond the scope of the current classification

5.3 Pre-submission meeting

5.3.1 Requesting a pre-submission meeting

Before filing a submission, the sponsor may request a pre-submission meeting with the VDD to seek regulatory guidance on specific items. The purpose of the meeting would be to:

- familiarize the VDD review staff with the information being submitted
- provide sponsors with specific guidance for the proposed submission
- help uncover any major foreseeable concerns or deficiencies with the submission and, in turn, help improve the quality of incoming submissions

- discuss the best approach to the presentation and formatting of data in the submission

Pre-submission meetings are not intended for presentation, discussion and pre-evaluation of actual data that have been generated from studies conducted by the sponsor. They are meant to provide further clarification and guidance on the type of studies and data needed in support of the submission.

The sponsor can send a meeting request to the VDD at any time. It takes approximately 60 calendar days to set up a pre-submission meeting from the date of the request. The sponsor should consider this time when planning to request a pre-submission meeting with the VDD.

The sponsor should send the meeting request to the VDD by e-mail using the pre-submission meeting request template located on our Forms - Applications and submissions - Veterinary Drugs website.

The sponsor should provide adequate product-related information to enable the review divisions to assess the meeting request and to select appropriate meeting attendees from the VDD. The VDD will log the meeting request and assign it a submission number.

Upon confirmation of the pre-submission meeting date, the VDD will notify the sponsor by e-mail. The sponsor needs to provide a pre-submission meeting package in electronic copy via e-mail by a specified date.

5.3.2 Pre-submission meeting package

Sponsors should note that pre-submission meetings are limited to 2 hours including a slide presentation (if any) of no longer than 30 minutes. When submitting pre-meeting packages, the sponsor should ensure the information submitted is sufficient to allow the appropriate feedback from the VDD. The VDD recommends the package be limited to 40 pages. It should contain:

- a cover letter outlining the purpose of the pre-meeting package
- a copy of the proposed meeting agenda
- the names and functions of the company's representatives that will attend the meeting
- a list of specific items or questions where guidance is being sought from VDD (grouped by scientific disciplines)
- a brief summary of the drug product (strength, dosage form, therapeutic claims and the intended species)
- a summary of the drug product concerning the chemistry and manufacturing, target animal safety and efficacy, and human safety (applicable if intended for use in food-producing animals) aspects of the product
- a copy of the proposed product label, if available
- an overview of the product registration status in Canada and in foreign countries
- proposed submission plan
- a copy of the presentation slides/handouts that are to be used during the meeting (if applicable)
- any other information that would be helpful for the meeting

5.3.3 Following the pre-submission meeting

After the pre-submission meeting, the sponsor needs to provide the VDD with a draft copy of the minutes of the meeting via e-mail within 2 weeks. The meeting minutes should include:

- meeting date, agenda and attendees from the VDD and the submission sponsor
- a copy of presentation slides/handouts used during the meeting if different from that submitted in the pre-meeting package
- a summary of key discussion items and outcome
- a list of follow-up items (if applicable)
- a version date for the draft minutes

Upon receipt of the draft meeting minutes, the VDD will try to review the minutes and provide a set of consolidated comments or accept the draft meeting minutes within 3 weeks. VDD attendees will need to accept the official record of the minutes.

Sponsors should include accepted pre-submission meeting minutes with the relevant future submission(s), with a rationale for deviation, when applicable.

6. Submission life cycle

6.1 Initial processing of submissions

Once a submission is administratively complete, the VDD will assign it a submission number. The VDD will send an acknowledgement of receipt to the sponsors for these submission types: NDS, ANDS, SNDS, SANDS, NC, DIN and ESC, including responses to notices of non-compliance (NON) as applicable. The VDD does not provide an acknowledgment of receipt for responses to clarification requests, screening deficiency notices (SDNs) or notices of deficiency (NODs).

The VDD will issue a screening acceptance letter for administrative NDSs and protocol reviews once the submission is administratively complete.

6.2 Submission screening

All submissions and related information (including responses to screening and review decision letters such as NODs) are subject to screening before being accepted for review. The purpose of screening is to ensure that submissions are prepared in an acceptable format and contain sufficient information to enable a proper review. The VDD also screens the submissions to ensure the sponsor has filed the correct submission type for the changes proposed, that is, it is not beyond the scope of the classification of the submission.

Submission sponsors should ensure that all relevant data is present at the time of filing or is available when the VDD requests it.

6.3 Deficiencies at screening

During the screening cycle, if the VDD finds the submission deficient, the VDD will send a clarification request or a screening deficiency notice (SDN) to the sponsor, seeking the outstanding information.

6.3.1 Clarification requests

The VDD may send clarification requests to the sponsor requesting further information or clarification that would enable the completion of screening. The information requested should be readily available as a clarification request wouldn't allow sufficient time for the sponsor to generate new data. The SKMD will send all clarification requests via e-mail.

The sponsor should send responses to clarification requests to the SKMD via email (see Appendix B for contact information). Upon receipt of a clarification request, the sponsor needs to provide a complete response to the VDD within the deadline indicated in the clarification request. The VDD will determine the deadline for response based on the extent and nature of the outstanding items, and will allow a reasonable timeframe for response. The sponsor may request extensions to clarification requests. The VDD will assess these requests on a case-by-case basis. If the VDD cannot accommodate the requested extension within the screening performance target, the VDD may consider putting the submission on inactive status pending a complete response. The VDD would then reset the screening clock upon receipt of a complete response.

6.3.2 Screening deficiency notice (SDN)

A sponsor's failure to respond to a clarification request will result in the issues, or remaining issues, contained in the clarification request being addressed through a SDN.

The VDD will primarily base a decision to issue a SDN on conditions including:

- omission of elements required by the *Food and Drugs Act* and regulations and applicable policies and guidances
- administrative omission or incomplete submission of required regulatory forms (if not addressed during initial processing or through a clarification request)
- scientific inadequacies in the submission such as omission of critical data, information or analysis needed to evaluate the quality, animal safety and efficacy and human safety of the drug or to support a proposed change
- poor presentation of a section (or the submission as a whole) that will preclude a proper review
- references to information or data submitted previously in a submission that is under review
- failure to address submission-related deficiencies that have been clearly communicated to the sponsor by the VDD during a pre-submission meeting or in regulatory correspondence prior to the sponsor filing the submission
- the addition of changes other than those stated in the submission with no supporting data

Following the receipt of a SDN, the sponsor needs to provide a complete response within the time specified on the SDN to address the deficiencies.

A new screening period will begin following the receipt of a response to a SDN. The VDD will only issue 1 SDN per screening cycle. If the VDD has already issued a SDN, it will issue a screening rejection notice (SRN) instead to address the remaining issues.

6.4 Screening decision

Upon the completion of screening, including the VDD's review of any responses to clarification requests or SDNs, the VDD will proceed with 1 of the 2 screening decisions:

- issuance of a screening acceptance letter
- issuance of a screening rejection notice (SRN)

6.4.1 Issuance of a screening acceptance letter

The VDD will base its decision to issue a screening acceptance letter on whether the submission is administratively complete and contains sufficient information to support the acceptance of the submission into review. At this point, the VDD will forward the submission to the relevant review division(s) and enter the first review cycle.

6.4.2 Issuance of screening rejection notice (SRN)

The VDD will base its decision to issue a SRN on conditions including whether:

- the submission is considered significantly incomplete or deficient and could not be reviewed without major modifications
- the response to the SDN is unsatisfactory or the sponsor fails to provide a response to the SDN within the specified deadline
- another submission to which the sponsor makes reference is still under review or the approval of the submission is dependent on a previously filed submission that is still under review
- the sponsor has filed a submission (for example, NC, SNDS or SANDS) relating to a product for which they do not hold the market authorization, unless the submission is also being filed for a manufacturer name change

6.5 Submission review period

Once the VDD has screened the submission and found it acceptable, the VDD will forward it to the relevant division(s) for review. The VDD will try to issue a decision letter within the performance targets outlined in Appendix A. The VDD will base the decision letter for the submission on the review outcomes from all relevant review divisions in Table 1.

Table 1. VDD review divisions and areas of focus	
VDD Review division	**Review focus**
Clinical Evaluation Division (CED)	• Animal safety and efficacy and pharmacovigilance • Labelling
Quality Evaluation Division (QED)	• Chemistry, manufacturing and controls • Labelling
Human Safety Division (HSD)	• Human safety: toxicology, residue, microbiological safety • Labelling
Submission and Knowledge Management Division (SKMD)	• Labelling (for review of administrative submissions only)

6.5.1 Communications during the review and clarification requests

The assigned reviewer(s) in each of the appropriate review divisions will review the data submitted. During the course of the review, the VDD may send clarification requests to the sponsor requesting further information or clarification that would help complete 1 or more review streams. A sponsor's failure to provide the information requested, in whole or in part, may affect the VDD's decision and could result in a negative decision letter (for example, notice of deficiency [NOD], notice of non-compliance [NON], refusal letter).

The regulatory project manager (RPM) will send all clarification requests by e-mail only, except administrative new drug submissions, which will be sent via the SKMD generic e-mail account. The information requested should be readily available. A clarification request would not allow sufficient time for the sponsor to generate new data.

Upon receipt of a clarification request, the sponsor needs to provide a **complete** response to the VDD within the deadline indicated in the clarification request.

The VDD will establish the response times for clarification requests based on the nature of the issues identified, per Table 2: Clarification request timelines.

Table 2: Clarification request timelines	
Response time	**Examples**
5 calendar days or less for minor issues	Typographical errors, minor clarifications, or minor revisions to documents that can reasonably be expected to be addressed within a short turnaround time
6 to 15 calendar days for all other issues	Safety/efficacy/quality clarifications, multiple minor issues in one clarification request, request for data that is known to be accessible to the sponsor (for example, bibliographical data), rationales or expert opinions, missing study information, initial request for complete labelling, PSUR requests

The VDD may also establish response times to accommodate specific circumstances, on a case-by-case basis, and with mutual agreement with the sponsor, as applicable.

The sponsor may request extensions to clarification requests. The VDD will assess these requests on a case-by-case basis. **Refer to the pause-the-clock section for more information.** The sponsor should address the response to the contact person(s) indicated in the clarification request.

6.5.2 Pause-the-clock during the scientific review

Pause-the-clock is a tool that allows the review clock to be paused under specified circumstances. When there is a pause, the target date is shifted to account for the amount of time the clock has been paused.

The review clock can pause only during the review period (for example, first review cycle and second review cycle) for cost-recovered submissions/applications. This mechanism excludes:

- administrative submissions/applications
- parallel or joint reviews with other regulatory authorities

A sponsor may request an extension to respond to a clarification request. The sponsor should submit the extension request as soon as possible in the form of a letter and written rationale.

The clock would pause if certain criteria are met:

- the extension request is beyond the number of days allocated to respond to a clarification request
- the extension request is a minimum of 5 days but not beyond 90 days per clarification request

- Health Canada approves the extension in writing to the sponsor

Following VDD's approval of the extension and after the standard clarification response time has elapsed, the review clock pauses. The sponsor has the additional time approved by Health Canada to respond to the request, and the target date is changed. Note that there may be situations where Health Canada would not approve an extension or grant an extension to an existing pause. The review clock would resume at the end of the approved extension period. If the response to a clarification request is not satisfactory or not submitted within the specified time to respond, a negative decision letter may be issued (this includes interim negative decision letters such as notices of deficiency).

6.6 VDD decisions

Once the VDD completes the review of the submission, it may issue different types of decisions, depending on the type of submission and outcome of the review.

6.6.1 For NDS, ANDS, SNDS, SANDS and administrative submissions

The VDD will issue a **notice of compliance (NOC)** if the submission complies with the regulations after a complete review of the submission by all relevant review divisions.

The VDD will issue a **notice of deficiency (NOD)** if it identifies outstanding deficiencies and/or significant omissions that preclude continuing the review. Deficiencies identified to date from all relevant review divisions will be included in the NOD. The sponsor needs to provide a complete response to the NOD within a specified deadline (see Appendix A). The VDD will only issue 1 NOD per submission.

The VDD will issue a **notice of non-compliance (NON)** if:

- a sponsor fails to provide a complete response to a NOD within the specified deadline
- the submission remains deficient following a complete review of the response to a NOD by the relevant review divisions

The VDD will include a rationale as to why the submission is considered not compliant along with a list of the specific deficiencies upon which the decision is based. The VDD will only issue 1 NON per submission.

Upon receipt of a NON, the sponsor may choose to refile the submission at a future time. The VDD will consider the refiled submission as a new submission. The sponsor should follow the instructions outlined in the refiled submission section of this document prior to refiling.

If the sponsor would like to request a reconsideration following receipt of a NON, they may contact the SKMD at vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca.

6.6.2 Other submission types and decisions

After a complete review of the submission by all relevant review divisions, the VDD may issue:

- a **no objection letter (NOL)** for an NC or IND if the submission complies with the regulations
- an **information satisfactory letter (ISL)** if a DIN or administrative DIN submission complies with the regulations
- an **approval letter** for a protocol review or change to DIN if the submission complies with the regulations
- an **experimental studies certificate (ESC)** if an ESC submission complies with the regulations
- a **notice of deficiency (NOD)** for a NC, protocol review, DIN, administrative DIN, change to DIN, ESC, ESC amendment where outstanding deficiencies and/or significant omissions preclude continuing the review. Deficiencies identified to date from all relevant review divisions will be included in the NOD. The sponsor needs to provide a complete response to the NOD within a specified deadline (see Appendix A). The VDD will only issue 1 NOD per submission.
- a **refusal letter** for a NC, protocol review, DIN, administrative DIN, change to DIN, ESC, ESC amendment (following review of a response to an NOD) or a **not satisfactory notice (NSN)** for IND. Upon receipt of a refusal letter/NSN, the sponsor may choose to re-file the submission at a future time. The VDD will consider the refiled submission as a new submission. The sponsor should follow the instructions outlined in the refiled submission section of this document prior to refiling.

6.7 Additional points to consider

Upon the receipt of a SDN, clarification request or NOD, the sponsor must respond within the time specified. If the sponsor cannot provide a response in the time specified, the sponsor may elect to withdraw the submission in place of receiving a subsequent negative decision. The sponsor should refer to the Guidance Document – Fees for the Review of Veterinary Drug Submissions and Applications when refiling a submission.

The sponsor should prepare all responses in a question and answer format with appropriate references to relevant sections of the original submission or information submitted previously. The sponsor must provide a detailed scientific explanation in the absence of the requested information.

The sponsor is encouraged to contact the designated person listed in the correspondence for clarification, when required.

7. Administrative amendments to submissions under review

At any time, the sponsors may provide administrative updates to submissions under review for changes to:

- product name
- manufacturer name
- regulatory contact information
- submission sponsor (if different from the manufacturer)

As part of the update, the sponsor needs to submit:

- a cover letter stating the nature of the administrative change
- revised drug submission application form, if applicable
- submission certification form, if applicable
- copies of the revised set of product labels and package inserts to reflect the change, if applicable
- a letter from the sponsor who filed the submission initially, authorizing the transfer of submission sponsorship to the new sponsor and the extent of the cross-reference permitted if the manufacturer of a submission has been changed resulting from a corporate merger, buy-out or licensing agreement

8. Post-approval obligations

8.1 Administrative submissions

The sponsor must file an administrative submission when there is a(n):

- merger/buyout
- change in product ownership
- change in the name of the manufacturer
- change in the product name (DIN, SNDS, SANDS submission)
- additional product name or licensing agreement between two manufacturers (DIN, NDS, or ANDS submission)

Prior to filing, the sponsor should ensure that the products have a clear registration record (for example, no outstanding issues/submissions that are still under review). To facilitate the review and approval process, the sponsor should limit the data provided to administrative content. Sponsors should file scientific updates under NC, SNDS, SANDS and change to DIN submissions.

The submission process for administrative submissions will be subject to the same management principles, procedures and processes outlined in previous sections of this document.

8.2 Transfer of business product lines

In the veterinary drug industry, one company may sell its entire business product line to another company through a commercial purchase transaction. To ensure regulatory compliance, both parties should consider the following points prior to, or even after, the completion of a business transfer:

- **marketing status of the product:** If the DIN of a product is dormant or cancelled, the new business owner of the product needs to refile a submission in order to obtain a valid DIN for marketing the product in Canada. The new sponsor should consult the VDD for specific guidance before filing a submission, should this be the case.
- **outstanding submissions that are still under review but were filed by the previous manufacturer/sponsor of the product:** The new sponsor needs an authorization letter from the sponsor of the previously filed submissions in support of the transfer of

submission sponsorship, if applicable. It is the new manufacturer's responsibility to determine the impact of the outstanding submissions on its marketing of the product in Canada.

8.3 Changes to a company's address and/or contact name

When there is a change in the company's address and/or contact name, the company needs to submit a letter to the Office of Submissions and Intellectual property (OSIP) at osip-bppi@hc-sc.gc.ca. The letter should state the nature of the changes and provide a list of affected products. The company can be a manufacturer, importer or any manufacturing site that holds an establishment license.

If the address change is related to the manufacturer, importer and/or distributor that is included on the labelling, revised labelling should also be submitted to VDD, along with an updated drug submission application form (DSAF) only for those submissions that are currently under review.

9. Cancelling a submission prior to approval

A sponsor may cancel a submission at any time. There may be implications for the fees payable depending on the timing of the cancellation. Please consult Guidance Document – Fees for the Review of Veterinary Drug Submissions and Applications for further information.

10. Refiled submission

A sponsor may refile a submission that was previously withdrawn, rejected, refused or for which a NON was issued.

The VDD will process all refiled submissions as new submissions and assign new submission numbers. They are subject to processing, screening and review as per this document. The refiled submissions are subject to the submission evaluation fees that are in place at the time of refiling.

A refiled submission is subject to any new policies, guidelines and procedures that may be in effect at the time of refiling.

Regardless of whether the related original submission was withdrawn, rejected or refused, , the sponsor must submit a complete set of information as required for all new submissions. It is not acceptable to:

- cross-reference to previously submitted information in lieu of resubmitting the information
- cross-reference to a submission that has not received a positive clearance (for example, NOC, ISL or a NOL)

Exceptions may apply in cases where an NON has been issued. If the submission is related to a NON issued for a previously filed NDS, ANDS, SNDS or SANDS submission, data requirements

are dependent on when the refiled submission is submitted. Refer to Table 3 for more information.

Table 3. Timing of refiling of a submission

Timing of refiling	Data requirement	Cross-reference to the original submission?
< 3 years from the date of NON	• Question and answer format to address deficiencies noted in NON • Submission certification that the information submitted in the original submission remains unchanged and is up-to-date (alternatively, the sponsors should provide a summary of the differences between the original submission and the refiled submission) • Drug submission application form	Yes
> 3 years from the date of NON	• Re-submit a complete set of information as required for all new submissions	No

11. Screening of unsolicited amendments to submission under review

The VDD does not accept unsolicited amendments to submissions already accepted for review unless the amendments meet certain criteria:

- the amendment consists only of additional animal safety or human safety information that will result in modifications to the contraindications, warnings, precautions and adverse reaction sections of the product labels and package inserts
- the amendment would enhance the safe use of the product in animals or provide a minimized impact on human safety or the environment
- the submission is under review as part of international regulatory cooperation, and the other participating regulator(s) required or requested the information
- the amendment contains other relevant information, as agreed to by the VDD and the sponsor

When submitting unsolicited amendments to submissions under review, the sponsor must integrate the amended information into the original submission and provide revised copies of the product labels and other affected documents as applicable.

12. Access to submission-related information

The sponsor should direct all inquiries regarding submission review status to the RPM assigned to the submission, if known. Otherwise, the sponsor can direct these inquiries to the SKMD via e-mail.

The RPM will try to provide a response within 3 working days to inform the sponsor regarding the review progress in the relevant review division(s).

The VDD will only respond to submission status inquiries for sponsors whose names are listed on the DSAF of the submission or to someone who is an authorized agent representing the submission sponsor. The VDD will not disclose any information in response to inquiries from third parties.

The sponsor should send all other inquiries via e-mail to the SKMD. This centralized procedure helps coordinate, track and respond to the high volume of inquiries from submission sponsors.

13. Drug submission evaluation fees

Prior to filing a submission, the sponsor should consult the fee-related documents to ensure they are using the appropriate fee assessment and following the applicable procedures.

- Guidance Document – Fees for the Review of Veterinary Drug Submissions and Applications
- Fees in Respect of Drugs and Medical Devices Order

Appendix A: Performance targets for veterinary drug submissions

Activity Type	Submission Type	Performance Target in Calendar Days (VDD)	Performance Target in Calendar Days (Sponsor)	Comments
Pre-submission meeting request	Pre-submission (NDS, ANDS, SNDS, SANDS, IND, NC, DIN, ESC, protocol review)	Not applicable	At least 60 prior to the proposed meeting date	Not applicable

Activity Type	Submission Type	Performance Target in Calendar Days (VDD)	Performance Target in Calendar Days (Sponsor)	Comments
Pre-submission meeting package	Pre-submission (NDS, ANDS, SNDS, SANDS, IND, NC, DIN, ESC, protocol review)	Not applicable	As specified by VDD in meeting confirmation	Not applicable
Draft pre-submission meeting minutes	Pre-submission (NDS, ANDS, SNDS, SANDS, IND, NC, DIN, ESC, protocol review)	Not applicable	14	Not applicable
Review of draft pre-submission meeting minutes	Pre-submission (NDS, ANDS, SNDS, SANDS, IND, NC, DIN, ESC, protocol review)	21	Not applicable	Not applicable
Screening	NDS, ANDS, SNDS, SANDS	45	Not applicable	INDs and protocol reviews are verified for administrative completeness only
	NC, DIN, change to DIN, administrative submissions	14		
	ESC/ ESC amendment	7		
	IND, protocol review	Not applicable		
Issuance of SDN	NDS, ANDS, SNDS, SANDS, Administrative new drug submissions, protocol review, DIN, administrative DIN, change to DIN	Not applicable	45	Once administratively complete, deficiencies for administrative submissions will

Activity Type	Submission Type	Performance Target in Calendar Days (VDD)	Performance Target in Calendar Days (Sponsor)	Comments
	NC, ESC, ESC amendment	Not applicable	30	be addressed during review. Protocol Reviews will not be scientifically screened and will either be accepted for review once administratively complete or rejected if the submission does not qualify as a protocol review.
Screening of response to SDN	NDS, ANDS, SNDS, SANDS, NC, DIN	14	Not applicable	Not applicable
	ESC	7		
Issuance screening acceptance letter	NDS, ANDS, SNDS, SANDS, administrative new drug submissions, protocol review, DIN, administrative DIN, change to DIN, NC, ESC, ESC amendment	Not applicable	Not applicable	Not applicable
Issuance of SRN	NDS, ANDS, SNDS, SANDS, administrative new drug submissions, protocol review, DIN, administrative DIN,	Not applicable	Not applicable	If the sponsor decides to refile this submission at a future time, it will processed as

Activity Type	Submission Type	Performance Target in Calendar Days (VDD)	Performance Target in Calendar Days (Sponsor)	Comments
	change to DIN, NC, ESC, ESC amendment			a new submission.
Issuance of clarification request	NDS, ANDS, SNDS, SANDS, administrative new drug submissions, IND, protocol review, DIN, administrative DIN, change to DIN, NC, ESC, ESC amendment	Not applicable	As indicated in clarification request	Not applicable
Issuance NOD	NDS, ANDS, SNDS, SANDS, administrative new drug submissions, DIN, administrative DIN, change to DIN	Not applicable	90	Not applicable
	NC, ESC, ESC amendment, protocol review	Not applicable	30	
Screening of response to NOD	NDS, ANDS, SNDS, SANDS, administrative new drug submissions, DIN, administrative DIN, change to DIN, NC, ESC, ESC amendment	Same as for initial submission	Not applicable	Not applicable
Review of initial submission	NDS, ANDS	300	Not applicable	Not applicable
	SNDS, SANDS	240		
	NC	90		

Activity Type	Submission Type	Performance Target in Calendar Days (VDD)	Performance Target in Calendar Days (Sponsor)	Comments
	Administrative NDS/ANDS/SNDS/SANDS	90		
	Protocol review, ESC/ ESC amendment, IND/IND amendment	60		
	DIN/administrative DIN/change to DIN	120		
Review of response to NOD (second review cycle)	NDS, ANDS	150	Not applicable	Not applicable
	SNDS, SANDS	120		
	DIN, administrative DIN, change to DIN, NC, ESC, ESC amendment, protocol review	60		
	Administrative NDS/ANDS and administrative SNDS/SANDS	45		

Appendix B: Contact information

Subject	Contact Address
All submission-related documents and requests except for product classification requests	E-mail: vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca

Subject	Contact Address
Product classification requests	E-mail: classification-vet@hc-sc.gc.ca
Regulatory Enrolment Process (REP)	E-mail: eReview@hc-sc.gc.ca

Appendix C: Definitions

Administrative submissions:

a submission that does not require scientific review. Includes NDS, ANDS, SNDS, SANDS, NC submission types.

Amendment to an ESC:

the request to amend an approved ESC, for example, require more drug product; change in study location; change in investigator.

Drug identification number (DIN):

an 8-digit numerical code assigned to each drug product.

Experimental studies certificate (ESC) submission:

information and material to support the issuance of an experimental studies certificate for a drug to be administered to either a food or non-food producing animal.

Investigational new drug (IND) submission:

a preclinical submission filed pursuant to Section C.08.005 of the *Food and Drug Regulations.*

Manufacturer:

company to whom the DIN number was assigned to for a given drug product.

Protocol review:

the request for the review of scientific information outside of a regular drug submission (that is, review of a proposed trial protocol).

Review:

the period from the time a submission is accepted for review to the time when a decision is made on that submission.

Screening:

the period from the time an administratively complete submission is received in the VDD to the time when a screening decision is made on that submission (also referred to as preliminary examination).

Sponsor:

the applicant who filed a drug submission with the VDD.

First review cycle:

the period during which the original submission is under review.

Second review cycle:

the period during which the response to a notice of deficiency is under review.