Health Canada Santé Canada

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# Post-notice of compliance changes of veterinary drugs: Level III form

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

Level III changes, or annual notifications, are post-notice of compliance (NOC) changes to a new drug that have minimal potential to impact the safety, efficacy, quality and/or effective use of the drug. The changes included in this reporting category may be implemented by the sponsor without prior review of the data supporting the change by Health Canada's Veterinary Drugs Directorate. Sponsors should use this form to file all Level III changes at the time they implement the proposed change or during the Annual Drug Notification period (Section C.01.014.5 of the *Food and Drug Regulations*). Please refer to the Post-Notice of Compliance (NOC) Changes: Guidance for quality of veterinary drugs or Post-Notice of Compliance changes: Guidance for safety and efficacy of veterinary drugs for more information.

The Regulatory Enrolment Process (REP) facilitates the filing and processing of certain regulatory information. Use of the REP is mandatory to file veterinary drug submissions that are within scope, which includes Level III changes. Detailed information regarding the REP is available on the REP information page. If you have any questions regarding the REP, please contact VDD at vdd.skmd.so-dgps.dmv.cp@hc-sc.gc.ca for more information, guidance, and support.

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

| **Section A – Product Information** |
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| Product (Brand) Name*: |
| Drug Identification Number (DIN)*: |
| Dossier ID*:<br>HC6-024- |
| **Section B – Level III Change(s)** |
| Type of Change*:<br>☐ Level III Quality – Fill out Section B-1<br>☐ Level III Safety & Efficacy – Fill out Section B-2 |
| Category of Change*:<br>☐ Drug substance<br>☐ Drug product<br>☐ Devices |
| Implementation Date (YYYY-MM-DD)*: |

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**Section B-1 – Level III Quality** (please check all that apply)

Note: The following options correspond with the change examples that fall under the Level III (annual notification) category as outlined in the Post-Notice of Compliance (NOC) Changes: Guidance for quality of veterinary drugs.

**Drug substance**

1- ☐ Change in the drug substance name/nomenclature

2- Changes to starting materials, involving:
- ☐ a) replacement or addition of a manufacturing site
- ☐ b) changes to the route of synthesis, with or without a change in manufacturing site

3- Changes to drug substance intermediates, involving:
- ☐ a) replacement or addition of a manufacturing site
- ☐ b) changes to specifications
- ☐ c) changes to the manufacturing process, with or without a change in manufacturing site

4- Changes to the drug substance manufacturing site, involving:
- ☐ a) replacement or addition of a manufacturing site
- ☐ b) addition of testing (e.g., release stability) site
- ☐ c) deletion of a manufacturing site

5- Changes to the drug substance when the manufacturing site has a valid Certificate of Suitability (CEP), involving:
- ☐ a) addition of a manufacturing site or a change to the manufacturing process
- ☐ b) replacement of a currently approved Active Substance Master File (ASMF) with a Certificate of Suitability (CEP)

6- ☐ Change in the manufacturing process for the drug substance

7- ☐ Change in the batch size for the drug substance

8- Change in the controls:
- ☐ a) for the materials used in the manufacture of the drug substance
- ☐ b) performed at critical steps in the process

9- Change in the:
- ☐ a) standard claimed for the drug substance (e.g., from a Professed to a Schedule B pharmacopoeial standard or from one Schedule B standard to a different Schedule B standard)
- ☐ b) specification for the drug substance to comply with an updated Schedule B pharmacopoeial monograph

10- Change in the specification for the drug substance involving test and acceptance criteria for:
- ☐ b) deletion of a test
- ☐ c) replacement of a test
- ☐ d) addition of a test
- ☐ e) relaxation of an acceptance criterion
- ☐ f) tightening of an acceptance criterion

11- Change in the specification for the drug substance involving analytical procedures for:
- ☐ a) deletion of an analytical procedure
- ☐ b) replacement of, alternate, or additional analytical procedure
- ☐ c) change from a House analytical procedure to a Schedule B analytical procedure, a change from an approved compendial analytical procedure to a harmonized compendial procedure, or from one Schedule B standard to a different Schedule B standard

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| 12- ☐ Change in the primary container closure system(s) for the storage and shipment of the drug substance |
| 13- Change in the re-test period (or shelf life) for the drug substance, involving:<br>☐ a) extension<br>☐ b) reduction |
| 14- ☐ Change in the storage conditions for the drug substance, involving: addition/deletion of a cautionary statement or relaxation/tightening of a temperature criterion |
| **Drug product:** |
| 16- ☐ Change in the composition of a solution dosage form |
| 17- ☐ Change in the composition of an immediate release dosage form (including a medicated premix) |
| 18- ☐ Addition, deletion or replacement of microtracer used in a medicated premix |
| 20- ☐ Change to product markings, involving a change in embossing, debossing, or engraving (except scorelines/break lines), or a change in imprinting |
| 21b- ☐ Change in scoring configuration, involving deletion of a scoreline |
| 22- ☐ Change in shape or dimensions of tablets, capsules, suppositories, or pessaries |
| 23b- ☐ Change in diluent, involving deletion of a diluent |
| 25- Replacement or addition of a drug product manufacturer / manufacturing site, involving:<br>☐ b) production of an immediate release product (e.g., tablet, capsule, liquids, semi-solids)<br>☐ c) primary packaging<br>☐ d) testing (e.g., release, stability)<br>☐ e) storage and distribution |
| 26- Change in the batch size for the drug product, involving:<br>☐ b) increase in batch size beyond a factor of 10 times for an immediate release drug product<br>☐ c) increase in batch size, up to and including a factor of 10 times<br>☐ d) a downscaling in the batch size) |
| 27- ☐ Change in the drug product manufacturing process |
| 28- Change in the controls (in-process tests and/or acceptance criteria) applied during the manufacturing process or on intermediates for:<br>☐ a) deletion of a test<br>☐ b) replacement or addition of a test<br>☐ c) relaxation or tightening of an acceptance criterion |
| 29- ☐ Change in the approved protocol for process validation and/or evaluation studies |
| 30- Change in the source of an excipient from:<br>☐ a) a vegetable, synthetic source, or non-TSE to a TSE risk source, or from a TSE risk to a different TSE risk source<br>☐ b) a TSE risk (e.g., animal) source to a vegetable or synthetic source |
| 31- Change in the:<br>☐ a) standard claimed for the drug product (e.g., from a Professed to Schedule B pharmacopoeial standard)<br>☐ b) specification for the drug product to comply with an updated Schedule B pharmacopoeial monograph |

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| 32- Change in the specification for the drug product tests and acceptance criteria, involving:<br>☐ b) deletion of a test<br>☐ c) replacement or addition of a test<br>☐ d) relaxation of an acceptance criterion<br>☐ e) tightening of an acceptance criterion |
| 33- Change in the specification for the drug product, for analytical procedures, involving:<br>☐ a) deletion of an analytical procedure<br>☐ b) replacement, alternate, or additional analytical procedure<br>☐ c) change from a House analytical procedure to a Schedule B analytical procedure, a change from an approved compendial analytical procedure to a harmonized compendial procedure, or from one Schedule B standard to a different Schedule B standard |
| 34- ☐ Change of specification for a veterinary drug product used in food producing animals |
| 36- Changes involving primary container closure system or package size:<br>☐ a) replacement or addition of a primary container closure system<br>☐ b) the change in the package size, involving change in the fill weight/fill volume<br>☐ c) change in the package size, involving a change in the number of units (e.g., tablets, ampoules) per package |
| 37- ☐ Change in qualitative and/or quantitative composition of any primary or functional secondary container closure component |
| 38- ☐ Change in the specification for a primary or functional secondary container closure component, involving deletion, replacement or addition of a test or; relaxation or tightening of an acceptance criterion |
| 39- Change in the shelf life for the drug product, involving:<br>☐ a) an extension<br>☐ b) a reduction |
| 40- ☐ Change in the product in-use stability period for an extension or addition |
| 41- Change in the labelled storage conditions for the drug product or the diluted or reconstituted product, involving:<br>☐ a) an addition of a cautionary statement<br>☐ d) tightening of a temperature criterion |
| 42- Change to the post-approval stability protocol for commitment or ongoing batches, involving:<br>☐ a) the addition of a time point at any time, or deletion of time points beyond the approved shelf-life<br>☐ b) changes to comply with a relevant VICH guidance (e.g., deletion of a time point from previously approved stability protocol, or change in storage conditions) |
| **Devices:** |
| 43- Change of an approved device used for the administration of a veterinary drug, involving:<br>☐ a) addition or replacement of a drug administration device that is not an integrated part of the primary packaging of a veterinary drug product<br>☐ b) deletion of a drug administration device that is not an integrated part of the primary packaging of a veterinary drug product<br>☐ c) a change in an approved multi-dose administration device for an injectable veterinary drug Product |

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| 44- ☐ Change to a device used for the administration of an extended-release veterinary drug [e.g. addition, deletion, replacement of, or change in materials of construction of an extended release device (e.g. for intra-ruminal boluses used for continued release) of a veterinary drug product] |
| 45- Minor changes to a device used for the administration of an extended-release veterinary drug, involving:<br>☐ a) the tightening of specification limits of an administration device for a veterinary drug (e.g. changes in balling gun used for intraruminal boluses to control drug product rate of release)<br>☐ b) a minor change to an approved test procedure<br>☐ c) the addition of a new test parameter |
| **Section B-2 – Level III Safety & Efficacy** (please check all that apply)<br>Note: The following options correspond with the change examples that fall under the Level III (annual notification) category as outlined in the Post-Notice of Compliance (NOC) Changes: Guidance for safety and efficacy of veterinary drugs. |
| 1- ☐ Any change to the layout of the label that does not represent a change to the requirements of Sections C.01.004 and A.01.016 of the Food and Drug Regulations (e.g., contrast, artwork, font, and position, or the terms of market authorization) |
| 2- ☐ Existing text of the labels have been revised to add clarity as it relates to maintaining consistency with common label phrase standards (e.g.,“Keep out of reach of children”) |
| 3- ☐ Any change in spelling of the text of the label (e.g.,'adition' is replaced by 'addition') |
| 4- ☐ Updating sponsor contact information (e.g., customer service number, website addresses, etc.) |
| 5- ☐ Other |
| **Please provide details of the change(s):** |

## Section C – Declaration (Select all boxes to confirm agreement)*

I, the undersigned, certify that:

- ☐ All of the products listed above are new drugs under Part C, Division 8 of the *Food and Drug Regulations* ;
- ☐ No changes have been made to the above products other than those Level III changes described herein;
- ☐ The information provided here with is complete and accurate;
- ☐ Complete supporting data (as recommended in the Post-Notice of Compliance Changes guidances for veterinary drugs) for the above changes is available upon request and has not been provided at this time; and
- ☐ The conditions/criteria in the Post-Notice of Compliance Changes guidances for veterinary drugs have been met.

## Section D – Information for the Authorized Signing Official and the Company to which they belong

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| Manufacturer/Sponsor Name (i.e. DIN/NOC Owner; full name, no abbreviations)*: | |
| Address of Manufacturer/Sponsor – Street/Suite/PO Box*: | |
| City/Town*: | Province/Territory/State*: |
| Country*: | Postal Code/Zip Code*: |
| Name of Authorized Signing Official*: | Title*: |
| E-mail*: | |
| Telephone*: | Facsimile: |

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