Notice - Revision to the Post-Notice of Compliance (NOC) Changes - Notices of Change: Level III Form

July 31, 2019

Our file number: 19-112939-775

1. Introduction

Revisions to change #2 (Appendix 1) have been made to the Guidance Document: Post-Notice of Compliance (NOC) Changes: Quality. The Level III changes form has been revised to reflect these changes. Please download form to your desktop before filling out.

Please note: Only the Level III changes form currently posted on the Health Canada website will be accepted.

2. When to file

A Post-Notice of Compliance (NOC) Changes (Level III) Changes form should be filed at the time the changes are implemented or annually during the Annual Drug Notification period depending on the type of drug (pharmaceutical or biologic) and the type of change made (Quality or Safety and Efficacy). Refer to Sections 2.1.3 and 2.2.4 of the Post-Notice of Compliance (NOC) Changes: Framework Document for more

detailed information on when to file Quality or Safety & Efficacy Level III changes and what documentation should be submitted when filing these changes.

Level III Changes should be filed for:

- New drugs that have received a Notice of Compliance (NOC) pursuant to section C.08.004 of the Food and Drug Regulations. These drugs may include pharmaceuticals, biologics, and radiopharmaceuticals for human use and pharmaceuticals, radiopharmaceuticals and certain biotechnological products for veterinary use.
- New drugs for which an NOC has been recommended but issuance of the NOC has been placed on hold.
- Drugs regulated under Part C, Division 1 of the Food and Drug Regulations that have received a drug identification number (DIN) pursuant to Section C.01.014.2 for Drug Identification Number applications - Biologic products (DIN-B).

Level III changes forms should not be provided for the following:

- Drugs regulated under Part C, Division 1 of the Food and Drug Regulations that have received a drug identification number (DIN) pursuant to Section C.01.014.2 for the following DIN types:
  - Drug Identification Number Application (DINA)
  - Disinfectant Drug Identification Number Application (DIND)
  - Category IV Monograph Drug Identification Number Application (DINF)
  - Veterinary Drug Identification Number Application (VDIN)

3. File Format and Content

Sponsors should complete a separate Level III changes form for each drug product and save them as separate PDF files.

A cover letter should not be provided in a regulatory transaction with a Level III Changes form.

Supporting data should not be provided with the Level III changes form. If additional information is required, it will be requested. Any unsolicited supporting data will not be reviewed.

4. How to File

Health Canada strongly recommends that all Post-NOC Changes: Level III changes forms be filed in eCTD format via the Common Electronic Submission Gateway (CESG). Refer to the Guidance Document: Preparation of Regulatory Activities in the Electronic Common Technical Document (eCTD) format for detailed instructions.

If not provided in eCTD format, the forms should be filed in "non-eCTD electronic-only" format. Refer to the Guidance Document: Preparation of Regulatory Activities in the "Non-eCTD Electronic-Only" format for detailed instructions.

Health Canada will not accept Level III changes forms provided in paper format.

Comments or questions should be directed to the Office of Submissions and Intellectual Property (OSIP):

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Date modified:

2019-07-30