Health Canada Santé Canada

March 19, 2013

Notice

Our file number: 13-103542-581

Re: The new requirements for submitting administrative drug submissions to Health Canada.

Health Canada is pleased to announce that effective immediately, administrative drug submissions which fall under the *Changes in Manufacturer's Name and/or Product Name policy* will be accepted in electronic only format. Administrative submissions in paper format will no longer be accepted as of June 1, 2013. This Notice has been amended to clarify that the above-noted change only applies to administrative submissions for human and veterinary drug products, and does not include administrative submissions for medical devices or natural health products.

All administrative submissions must be submitted to Health Canada electronically on compact disc/digital versatile disc (CD/DVD); **No paper copy of the administrative regulatory activity should be submitted**. Electronic documents will be uploaded onto the Health Canada viewing tool, where they will be immediately accessible to Health Canada staff involved in the review of the submission. This will contribute to good record management and ensure authenticity, integrity, availability, traceability, and non-repudiation of the data. Health Canada would like to remind sponsors not to include credit card, wire, or cheque payment information with electronic submissions. Please see the Notice on the Health Canada website for more information.

Administrative submissions must be submitted with a cover letter, in both electronic **and** paper, which clearly explains the intent of the package and details the reason for the submission (such as *cross licensing agreements*, *product name changes*, *company name changes*, etc.).

1 Folder Structure and Folder Content

The content of the electronic media should be organized in folders. **Files submitted electronically should not be zipped** or **password protected.**

- With the exception of the file extension, the file naming convention within each folder is left to the sponsor. However, Health Canada suggests that the file names be kept as brief and meaningful as possible.
- The International Conference on Harmonization (ICH) requires that the file names be limited to a maximum of 64 characters, including the file extension. See the ICH *Electronic Common Technical Document Specification* (Version 3.2), "Name," pages 2-5.

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1.1 Electronic Common Technical Document (eCTD) Requirements

Administrative submissions submitted in eCTD are the preferred format by Health Canada. Sponsors should refer to the *Draft Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document (eCTD) Format* and the *Guidance Document: Creation of the Canadian Module 1 Backbone*, for preparing submissions in eCTD format.

1.2 Non-eCTD Requirements

When administrative submissions are not submitted in eCTD format, they should be sent electronically as portable document format (PDF) files, with the exception of labelling documents such as product monographs, which must be in an editable file format. The submission should be filed in folders and should be named according to the information provided in *"Appendix D: Common Technical Document (CTD) Format"* of the *Guidance Document: Preparation of Drug Regulatory Activities in the Common Technical Document (CTD) Format*. The electronic document is the legal document for the submission in non-eCTD format.

2 Media for Submitting Electronic Data

The media formats acceptable when submitting any electronic submission are:

- Compact Disc-Recordable (CD-R) conforming to the Joliet specification;
- Digital Versatile Disc-Random Access Memory (DVD-RAM) Universal Disc Format (UDF) standard;
- Digital Versatile Disc-Recordable (DVD+R/-R) recorded in the Universal Disc Format (UDF) standard.

These are the formats that are currently supported. Contact the Office of Submission and Intellectual Property (OSIP) for other formats that may be acceptable at the time of filing. See below for full contact information.

Media should not be password protected. Sponsors should provide all documents on a single disc. Duplicate copies are not required.

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All media should be labelled. The label on the disc should contain the following information:

- Sponsor name and brand name;
- eCTD Identifier *(if applicable)* ;
- Sequence number *(if applicable)* ;
- "Protected B"[1];
- Virus-free certification, the software used for the virus check, and the date of the virus definition file or files; and
- Month and year of filing.

Subsequent to burning the CD or DVD, sponsors should ensure that **all** files can be opened and that no files are corrupt.

3 Contact Information

Office of Submissions and Intellectual Property (OSIP)
Therapeutic Products Directorate (TPD)
Health Canada
Address Locator 0201A1
101 Tunney's Pasture Driveway
Ottawa, Ontario
K1A 0K9

E-mail: ereview@hc-sc.gc.ca

[1] "Protected" status identifies information the unauthorized disclosure of which could reasonably be expected to cause injury to private interests. "Protected B" indicates a medium degree of potential injury. See *Government Security Policy* (July 2009), Section 10.6, "Identification of Assets." The policy is available at http://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=12322.