July 21, 2016

DEL Bulletin

Changes to the application process related to Foreign Buildings listed on Drug Establishment Licences

Dear Stakeholders,

This DEL Bulletin is to inform you of a change to the foreign building evidence submission process to reduce regulatory burden. This information is important to importers and/or drug submission sponsors seeking to import from a foreign building.

Background

As per section C.01A.008 of the *Food and Drug Regulations* (FDR), when a drug is fabricated, packaged, labelled and/or tested outside of Canada, the foreign building where those activities occur must be listed on the Drug Establishment Licence (DEL) held by the Canadian importer. For the foreign building to be listed on the DEL, it must be deemed compliant with Good Manufacturing Practices (GMP) requirements as described in Division 2 to 4, Part C of the FDR. Importers of finished dosage forms must submit evidence as per the *Guidance on Evidence to Demonstrate Drug GMP Compliance of Foreign Sites (GUI-0080)*, as part of your DEL application, pursuant to C.01A.005 of the FDR.

Until now, and in accordance with GUI-0080, foreign buildings have been listed on your DEL Foreign Building Annex with an expiry date based on the GMP evidence you provided to Health Canada. DEL holders were previously expected to submit an application with the updated GMP evidence 250 days prior to the expiry date to prevent removal of expired foreign buildings from your Foreign Building Annex.

PART A – Foreign buildings located in non-MRA countries listed on the Foreign Building Annex

Effective immediately, the "New Evidence Required By" (NERBY) date replaces the "Expiry Date"/ Validity of Evidence Date.

Effective as of the date of this Bulletin, importers are no longer asked to submit the updated GMP evidence 250 days prior to the buildings expiry date. As long as an application is submitted in accordance with the FDR including complete and updated GMP evidence, by the foreign building's NERBY date, the foreign building will continue to be considered GMP compliant and listed on your DEL Foreign Building Annex. During the assessment of your

evidence, you may continue to import drugs from the foreign building in accordance with your DEL and the FDR. Should the application not be received by the NERBY date or if the evidence is deemed unacceptable or incomplete at any time in the assessment process, the foreign building may be removed from your Foreign Building Annex. Once a foreign building is removed from your DEL, you are no longer authorized to import from this building and you will be notified. You must submit a complete application to Health Canada to add the building back onto your DEL respecting the 250-day timeline for processing a DEL application.

Upon receipt of your DEL application with appropriate foreign building GMP evidence, Health Canada will send you an Acknowledgement of Application Acceptance email, as per the current practice. Health Canada will also send you a Screening Acceptance Notice to notify you that the GMP evidence has been screened and accepted for further review.

Implementation

In cases where a foreign building was removed from the DEL Foreign Building Annex because the GMP evidence expired, the foreign building will be re-instated if a complete application is under review with Health Canada. If a complete application is not under review, the foreign building will be removed from the licence. As of this date, if the expiry date has passed but the building remains listed, you may continue to import drugs from the foreign building in accordance with your DEL and the FDR. Expiry dates will be changed to NERBY on printed licences as applications are processed and amended licences are issued over time.

Determination of the NERBY date

The NERBY date will be determined using a risk-based approach. The NERBY date will generally be 4 years, calculated from the start date of the inspection. However, Health Canada may issue a shortened or extended NERBY date for a foreign building based on several factors, including but not limited to the building's compliance history and the category of the drug. In the event that new GMP evidence is unavailable, you may request an inspection of the foreign building by Health Canada, as per the *Guidance on Evidence to Demonstrate Drug GMP Compliance of Foreign Sites* (GUI-0080).

Health Canada will not take a retroactive approach in amending past expiry dates to reflect the new NERBY date policy. In the interim, if a foreign building was subject to a 3-year expiry date and does not have updated GMP evidence by the NERBY date, importers may request an extension by sending a rationale to foreign_site_etranger@hc-sc.gc.ca.

PART B - Foreign buildings listed on the Active Pharmaceutical Ingredient (API) Foreign Building Annex

A NERBY date will not be added to the DEL for API foreign buildings listed on the API Annex.

As per current process, Health Canada employs a risk-based approach to select foreign API manufacturers to request comprehensive GMP evidence in the accordance with the July 31, 2015 Notice - *Updates to drug establishment licence applications and good manufacturing practice evidence requirements for active pharmaceutical ingredients*. During this assessment process, importers may continue importation until Heath Canada communicates otherwise. Upon completion of the assessment a NERBY date will not be assigned as the evidence will be requested by Health Canada.

PART C - Foreign buildings located in MRA countries listed on the Foreign Building Annex

Health Canada no longer asks DEL holders to submit an application to renew the GMP evidence of a foreign building located in a MRA country on the DEL.

Effective as of the date of this Bulletin, Health Canada proactively requests Certificates of Compliance (CoC) from Mutual Recognition Agreement (MRA) partners to reduce regulatory burden. In light of this, Health Canada will not assign a NERBY date for these buildings, where the GMP evidence was solely a CoC. Should the MRA partner inform Health Canada that a CoC cannot be issued due to the foreign building no longer holding a valid permit, licence or other authorization, you will be notified and the foreign building will be removed from your DEL in accordance with section C.01A.015 of the FDR.

Implementation

The process change takes effect now, ahead of expiry dates being removed from the printed DEL. Therefore, if the expiry date has passed but the building remains listed, you may continue to import drugs from the foreign building in accordance with your DEL and the FDR. In cases where a foreign building was removed from the DEL Foreign Building Annex due to the expiry of the CoC, the foreign building will be re-instated as long as the MRA partner has not informed Health Canada that a CoC cannot be issued. For those buildings that are not covered by the MRA GMP evidence will be required and these buildings will have a NERBY date (see Part A).

PART D – COMPLIANCE AND ENFORCEMENT

As per C.01A.013 of the FDR, you are responsible to notify Health Canada of events that result in a contravention of any of the applicable requirements under Divisions 2 to 4 of the FDR, where it may affect the quality, safety or efficacy of a drug fabricated, packaged/labelled, tested as required under Division 2 or stored by them.

Health Canada will continue to take appropriate actions, where needed, to protect the health and safety of Canadians pursuant to the *Food and Drug Act* (FDA) and its *Regulations,* and its compliance and enforcement policies. Be reminded that you may request at any time the removal of foreign buildings from your Foreign Building Annex based on your business needs.

Contact us

Should you have any questions regarding the DEL application process or process changes related to the NERBY date, please contact the Establishment Licensing Unit at:

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

Telephone: (613)618-4529
Facsimile: (613) 957-4147
Teletypewriter: 1-800-465-7735 (Service Canada)

Should you have any questions related to foreign building GMP evidence, determination of the NERBY date or extensions, please contact the Drug GMP Inspection Unit at:

E-mail: foreign_site_etranger@hc-sc.gc.ca
Facsimile: 613-957-6709
Teletypewriter: 1-800-465-7735 (Service Canada)