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HPFB Inspectorate: Establishment Licensing Important: Upcoming Changes

Upcoming Changes

Repeal of Establishment Licence Expiry Date

Effective April 1, 2011, an establishment licence will no longer expire on December 31 of each year. Pursuant to section C.01A.009(1)(2) of the *Food and Drug Regulations*, a licence will continue to be valid, as long as an application for Annual Review is submitted before April 1 of each year. Upon completion of an assessment of an application, the Inspectorate will communicate its decision, which can include a notice of no objection or a notice of suspension, to the licence holder. If there is no objection, the activities noted on the establishment licence may continue to be conducted.

Regulations Amending the Food and Drug Regulations
http://gazette.gc.ca/rp-pr/p1/2010/2010-11-13/html/reg6-eng.html

Cost Recovery Initiative and Implementation of Performance Standards

Effective from April 1, 2011, performance standards for the issuance of establishment licences will be implemented. The standards are 120 days for the issuance of a medical device establishment licence and 250 days for the issuance of a drug establishment licence. If the information and material accompanying an application is deemed acceptable to enable further processing, the application will be accepted for review. Tracking of performance standards will commence from the date of acceptance for review.

Applicants who **have** completed one calendar year of conducting activities under an establishment licence **must submit at the time of application:** payment, a Fee Form, a completed Calculation Chart, and a Certified Statement, if they wish to be considered for a fee remission.

Applicants who **have not** completed one calendar year of conducting activities under an establishment licence will have their payment deferred by one calendar year.

Also, effective from April 1, 2011, changes to the user fee regulations will be implemented. These changes include: new fees for drug and medical device establishment licences, annual adjustment of fees, changes to the timing of payment, and new fee mitigation measures. For more information on new fees and fee requirements please see the following regulations:

Fees in Respect of Drugs and Medical Devices Regulations
http://gazette.gc.ca/rp-pr/p1/2010/2010-11-13/html/reg2-eng.html

Regulations Amending the Establishment Licensing Fees Regulations
http://gazette.gc.ca/rp-pr/p1/2010/2010-11-13/html/reg4-eng.html

Regulations Amending the Licensed Dealers for Controlled Drugs and Narcotics Fees Regulations
http://gazette.gc.ca/rp-pr/p1/2010/2010-11-13/html/reg5-eng.html

Applicant/Licence Holder Responsibility

When the regulations repealing the expiry date come into effect on April 1, 2011, establishment licence holders will be required to submit an application for Annual Review before April 1 of each year. Failure to submit an application for an Annual Review renders the establishment licence invalid.

New Applicants
After April 1, 2011, all licences issued to first time applicants will not indicate an expiration date; however, the following annexes will continue to have expiration dates: foreign site, alternate sample retention site and terms and conditions. For companies that have been issued an establishment licence with no expiry date, their annual review application will be due by April 1, 2012.

Current Licence Holders
Establishment licences issued with a December 31, 2011 expiry date will be considered valid until April 1, 2012, unless they have non-compliant domestic or foreign site evidence, or are subject to Terms and Conditions.

The renewal process currently used will be replaced by an annual review. The 2012 annual review process will begin in the summer of 2011 by sending notices to all licence holders. This change will allow the Inspectorate to issue all 2012 licences (with no expiry date) by April 1, 2012.

Applications for annual review **must** be submitted to the Inspectorate before April 1, 2012. The Inspectorate will initiate the 2012 Annual Review process by sending notices to all licence holders in summer 2011. In order to enable the Inspectorate to issue all 2012 licences (with no expiry date) by April 1, 2012, all licence holders are encouraged to respond to the Annual Review notice within 30-60 days of receipt.

Note: Procedures for Cells, Tissue, Organ (CTO) registration, Certificate of a Pharmaceutical Product (CPP) and Manufacturers Certificate of Export for Medical Devices (MCE) remain unchanged.

How to Apply

For more information on establishment licensing and the recent changes, please refer to: www.healthcanada.gc.ca/establishmentlicences

Contact Information:
DEL Email: del_questions_leppp@hc-sc.gc.ca
MDEL Email: mdel_questions_lepim@hc-sc.gc.ca
FEE Email: eliu_ufle@hc-sc.gc.ca

Applications to be sent to:
Establishment Licensing Unit
Health Products and Food Branch Inspectorate
250 Lanark Avenue, Address Locator 2002A
Ottawa, ON K1A 0K9

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