Regulatory and Policy Updates
Therapeutic Products Directorate
Health Canada

Cindy Evans
Director, Medical Devices Bureau
Therapeutics Product Directorate
Decorative Contact (Non-Corrective) Lenses

- Amendment to the *Medical Devices Regulations* for Non-Corrective Contact Lenses (NCCL) and Labelling of Class II medical devices was published in Canada Gazette II on July 29, 2015.
Decorative Contact (Non-Corrective) Lenses

- These regulatory changes introduce two changes to the Medical Devices Regulations in respect of licence application requirements for Class II medical devices including one to give effect to the *Bill C-313 An Act to Amend the Food and Drugs Act* which received Royal Assent on December 14, 2012
Decorative Contact (Non-Corrective) Lenses

• As part of the work to classify non-corrective contact lenses (NCCLs) as devices under the *Food and Drugs Act* and to license them under the *Medical Devices Regulations*, the first amendment exempts manufacturers of NCCLs from the regulatory requirement to establish therapeutic effectiveness as these products have no therapeutic effect.

• These amendments come into force on July 16, 2016.
Decorative Contact (Non-Corrective) Lenses

• The second amendment requires manufacturers of all Class II medical devices (including non-corrective contact lenses) to begin submitting copies of their product labels as part of their licence application.

• This amendment comes into force on July 16, 2015.
Regulatory Transparency and Openness Initiatives

• Posting of Regulatory Decision Summaries
  • Positive decisions for new Class IV medical device licence applications filed after April 1, 2015
  • Negative decisions for new Class IV medical device licence applications filed after April 1, 2016
Final Guidance Documents

• Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs) published on June 12, 2015.

• Notice on electronic labelling of certain medical devices sold or imported into Canada published on June 26, 2015

• Guidance on Labelling of Medical Devices, Not Including In Vitro Diagnostic Devices published on July 29, 2015