Drugs and Health Products

Notice – Applications for Investigational Testing Authorization (ITA), for Medical Devices, in the "Non-eCTD Electronics-Only" Format

January 3, 2017
Reference number: 16-115240-468

Health Canada is announcing that as of January 1st, 2017, applications for Investigational Testing Authorizations (ITAs) for Medical Devices will be accepted in the “non-eCTD electronic-only” format.

Refer to the Guidance Document: Preparation of Regulatory Activities in "Non-eCTD Electronic-Only” Format for detailed guidance on filing medical device regulatory activities and subsequent transactions, in the “non-eCTD electronic-only” format.

This Notice serves as an update to the Guidance Document: Preparation of Regulatory Activities in the "Non-eCTD Electronic-Only” Format to expand the scope of medical device regulatory activities to include ITAs.

As per the specified guidance, as of April 1st, 2017, Health Canada will no longer accept paper copies of regulatory activities or their related transactions, including ITAs.

The attached zipped folder structure can be used by adding documents in their respected folders. Empty folders must be deleted before filing to Health Canada.

Medical Devices ZIP (Zip Version - 9.9 K)

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