NOTIFICATION

Addendum

The following communication, dated 21 March 2019, is being circulated at the request of the delegation of Canada.

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Regulations Amending the Food and Drug Regulations (Public Release of Clinical Information): SOR/2019-62

Regulations Amending the Medical Devices Regulations (Public Release of Clinical Information): SOR/2019-63

The proposed regulatory amendments notified in G/TBT/N/CAN/536 (dated 14 December 2017) were adopted and published on 20 March 2019 as the Regulations Amending the Food and Drug Regulations (Public Release of Clinical Information) and Regulations Amending the Medical Devices Regulations (Public Release of Clinical Information).

The changes are intended to provide public access to clinical information submitted to Health Canada in drug submissions for human use and medical device applications.

These Regulations came into force on the day on which they were registered (4 March 2019).

The full text of the adopted measure can be downloaded from the Internet addresses below:

<http://www.gazette.gc.ca/rp-pr/p2/2019/2019-03-20/html/sor-dors62-eng.html> (English)

<http://www.gazette.gc.ca/rp-pr/p2/2019/2019-03-20/html/sor-dors62-fra.html> (French)

<http://www.gazette.gc.ca/rp-pr/p2/2019/2019-03-20/html/sor-dors63-eng.html> (English)

<http://www.gazette.gc.ca/rp-pr/p2/2019/2019-03-20/html/sor-dors63-fra.html> (French)

or requested from:

Canada's Notification Authority and Enquiry Point

Global Affairs Canada

Technical Barriers and Regulations Division

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